

AN INNOVATIVE STRATEGY TO INCREASE PATIENT HAND HYGIENE
AUTONOMY OF HOSPITALIZED ADULTS

by

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An Innovative Strategy to Increase Patient Hand Hygiene Autonomy of Hospitalized

Adults

by

SHANINA C KNIGHTON

Abstract

Despite recognition that patients carry pathogens on their hands and demonstrate poor hand hygiene practice, little attention has been given to interventions that increase hand hygiene practices of patients. Studies that have attempted to improve patient hand hygiene practice lack sustainability due to dependability on healthcare staff, however no prior studies have considered ways to improve independent patient hand hygiene practice. One such approach is using a multi-modal education intervention centered around patients that will promote patient self-practice.

The purpose of this comparative effectiveness study was to test the effectiveness of two educationally-based approaches to improve patient hand hygiene in older adults hospitalized for elective lower extremity orthopedic or podiatry surgery at a veterans' hospital. Group 1 (n=41) received an educational video, an educational handout/model (Four Moments for Patient's Hand Hygiene) and a voice-recorded electronic audio reminder (EAR), which verbally reminded the participant to clean their hands. Group 2 (n=34) received only the educational video and Moments for Patient's Hand Hygiene "Four Moments" handout.

Comparing Post-operative Day (POD) 0 to up to POD 3, and controlling for covariates (Disability of Arm, Shoulder, and Hand [*QuickDASH*], Hand Grip Strength, Surgical Pain, MRSA in Nares), the questions asked were if participants in the Group 1

had better rates of patient hand hygiene behavior as measured by product consumption and the quantity of colony-forming units on their hands.

Using multivariate and univariate analyses, results indicated that the electronic audio reminder was a significant predictor of ABHR consumption, $R^2 = .39$, $R^2_{adj.} = .34$, $F(6, 68) = 7.265$, $p < .001$. The average product consumption of ABHR in Group 1 was 29.97 grams (SD 17.13); in comparison to Group 2, 10.88 grams (9.27) ($p < 0.0001$). A subset of participants' hands were cultured from each group on Day 0 and Day 3, both groups were negative for bacterial growth of both gram-negative and or MRSA pathogens.

Implications from this study demonstrate that simple audio technology has the potential to increase patient-centered infection prevention in the acute care settings without increasing healthcare worker burden. Findings can be used to promote healthy behaviors, prevent infection and disease, and improve patient-centered care.

Chapter I

The study was to improve patient hand hygiene in older veterans hospitalized for an elective lower extremity surgical intervention. The 2-group comparison design tested the effectiveness of two educationally-based multimodal approaches to improve patient hand hygiene in older veterans hospitalized for elective lower extremity orthopedic or podiatry surgery. Group 1 received an educational video, an educational handout (passive cue to action), and an electronic audio reminder (EAR) an *active cue to action*, which reminded participants to clean their hands three times during wake hours with alcohol based hand rub (ABHR). Group 2 received the educational video and 'Four Moments' handout only.

The two-group comparison design had a sample of 75 veterans, ages 55 years and older admitted to a surgical unit in an urban Veterans Affairs Medical Center (VAMC). Participants were randomly assigned to one of the two groups (education intervention with the EAR and education intervention only) using randomization software. The study site, Ward 5A, is a 36-bed surgery unit in the academically affiliated Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC); patients who receive hip or knee surgeries account for approximately 22% of the surgical caseload per week (Personal Correspondence: MA Bobulsky, Quality Management, LSCVAMC, April 15, 2015). Average length of stay for orthopedic and podiatry surgical operation recovery is 3-5 days. All patient rooms on the medical surgical units have a room sink with a soap and paper towel dispenser, a private bathroom, and a hand sanitizer dispenser at the door entrance.

Participants were enrolled in the study following admission to surgical ward (from the post-anesthesia care unit) and enrolled ≤ 12 hours of surgery. Data collection immediately began following enrollment, on post-operative day one, post-operative day two and on post-operative day three. The primary clinical outcome was patient hand hygiene practice as measured through the amount of alcohol-based hand rub used in a three-day period. A secondary clinical outcome was the identification of pathogens (Methicillin Resistant *Staphylococcus aureus* and Gram-negative organisms) on participants' hands.

Background

One of the goals of the nursing profession is to save or improve lives by providing patients with the optimal environment to heal (Heitkemper & Bond, 2003). Yet, the reality is that hospitalized patients are at risk for increased morbidity and mortality because of an infection contracted during their hospital stay. These infections are commonly known as healthcare-associated infections (HAIs). According to the Centers for Disease Control and Prevention (CDC), HAIs are infections acquired in the healthcare setting (e.g., admission to the acute care, hemodialysis, ambulatory care, or outpatient surgical care) for which there is no evidence indicating that it was present or incubating during or before the patient's admission (Horan, Andrus, & Dudeck, 2008).

Healthcare-associated infections significantly impacts healthcare delivery and length of stay, with associated costs ranging from \$28,000-\$127,000 per infection (Elaine Larson, 2013; Stone, 2009) and affects more than two million Americans annually (Stone, 2009). Each year, in the United States there are approximately 440,000 HAIs that occur amongst inpatient adults. Surgical-site infections (a type of HAI) account

for approximately one-third of these infections of which Methicillin-Resistant *Staphylococcus aureus* (MRSA) and Gram-negative (Gram [-]) bacteria are the most prevalent pathogens (Nelson et al., 2015; Peleg & Hooper, 2010; Wong, Chen, Win, Ng, & Chow, 2015; Zimlichman et al., 2013). Additionally, the majority of the pathogens associated with surgical site infections involve the patient's own organisms (Reichman & Greenberg, 2009; Stevens et al., 2005). Numerous studies report that the physical environment of the hospital setting, including medical equipment and high touch surfaces are frequently contaminated and have the potential for harboring pathogens (Hota, 2004; Hota et al., 2012; Weber & Rutala, 2013). Patients often encounter objects in the environment.

For the past 165 years, studies have overwhelmingly demonstrated that hand hygiene is the single most important way to prevent the spread of pathogens that lead to healthcare-associated infections (Borg et al., 2009). Hence, The Joint Commission and World Health Organization established national standards for hand hygiene compliance of healthcare workers. The effectiveness of healthcare worker hand hygiene education and behavior has been measured by alcohol-based hand rub (ABHR) product consumption (Boyce, 2011; Boyce, Pittet, Healthcare Infection Control Practices Advisory Committee, & HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, 2002) and the amounts of colony forming units (presence of bacteria) identified on healthcare workers' hands (Burton et al., 2011; De Alwis et al., 2012; Landelle et al., 2014; Sanderson & Weissler, 1992). In contrast while pathogens such as MRSA and Gram [-] bacteria have been identified on the hands of patients (Istenes, Bingham, Hazelett, Fleming, & Kirk, 2013; Peleg & Hooper, 2010; Sunkesula, Kundrapu, Macinga, &

Donskey, 2015), few studies investigate the use of strategies to improve patient hand hygiene in the acute care setting. Hand hygiene is considered a behavior learned during childhood, which becomes a habit of daily care as a result of lifestyle (CDC, 2015). However, patients' concerns and ability to complete even the simplest habitual hygiene tasks are often overlooked when in the hospital setting (McGuckin, Shubin, & Hujcs, 2008).

One study found that there was *no use* of ABHR by 151 study participants (Savage, Fuller, Besser, & Stone, 2011). An observational study showed that staff-initiated patient hand hygiene events (97.3% (428/440), were significantly higher than patient self-initiated hand hygiene (37.5%, 218/582), $p < .001$) (Cheng et al., 2016). Other studies report that while patients recognize the importance of hand hygiene (Barker et al., 2014; Burnett, Lee, & Kydd, 2008), they rarely practice it while in the hospital (Almaguer-Leyva et al., 2013; Savage et al., 2011; Srigley, Furness, & Gardam, 2014).

One solution to this challenging problem is to hold nurses and/or staff accountable for patient hand hygiene. A study conducted in a 250-bed community hospital showed that nurses cleaning patients' hands twice a day for one year yielded a 51% MRSA reduction rate and nearly \$688,000 (Canadian Dollars) in savings (Gagné, Bédard, & Maziade, 2010). While a nurse-initiated approach to patient hand hygiene can be effective, obstacles exist. One study identified nurses' workload as an obstacle to an educational intervention designed for nurses to help improve patient hand hygiene (Ardizzone, Smolowitz, Kline, Thom, & Larson, 2013). Thus, while this could be an effective approach it would be at the cost of increasing the nurses' pre-existing heavy workloads, which are known to contribute to patient safety errors, job dissatisfaction and burnout

(Carayon & Gurses, 2008; Cimiotti, Aiken, Sloane, & Wu, 2012; Poghosyan, Clarke, Finlayson, & Aiken, 2010). A study attempting to improve independent patient hand hygiene practice found that providing patients with education and resources, the ‘Patient’s Four Moments for Hand Hygiene’ (Four Moments) handout and a hand sanitizer bottle at the bedside was not sufficient to change behavior (Sunkesula, et al., 2015). Although 96% of patients reported patient hand hygiene to be of importance, only 13% were observed to practice (Sunkesula et al., 2015). During the second phase of this intervention, a verbal *reminder* from food service workers and the provision of wipes during mealtimes was associated with an increase of patient hand hygiene (8% to 79%) (Sunkesula et al., 2015). Continued testing of reminders, particularly *technology-based reminders*, is a logical next step. One option is an electronic audio reminder (EAR). From automobiles to phones, audio reminders are widespread, effective, and accepted by all ages.

Consequently, it is imperative that nurse scientists investigate innovative methods to safely reduce HAIs in hospitalized patients without increasing nurse workload. Minimizing the significant iatrogenic consequences of HAIs requires that individuals in the hospital environment use a systematic and multifactorial approach for infection prevention. This study will test an approach of an electronic reminder and an educational video to increase self-management of hand hygiene behavior in hospitalized adults older than 55 years of age who have non-emergent lower extremity (LE) surgery. The surgical population was targeted due to the risk of cross-contamination to surgical wounds as result of patients being exposed to themselves, healthcare workers, and the environment (Kaye, Schmader, & Sawyer, 2004; Kvasnovsky et al., 2015). Using an electronic

reminder, educational video, and handout as a part of the intervention protocol), the Primary Investigator (PI) 1) educated veteran participants via video, handout and teach back to help them learn how and when to cleanse their hands with an alcohol-based hand rub and 2) assessed differences in rates of adherence to hand cleansing practice post the random assignment of an electronic reminder. As one of the first studies testing an intervention to increase the independent practice of patient hand hygiene in the hospital setting, the findings from this research will contribute to the growing body of science on the effectiveness of hand hygiene for patients.

Theoretical Framework

The framework for this study was drawn from Virginia Henderson's Concept of Nursing (Henderson, 1966), the Human Response Model (Heitkemper & Bond, 2003) and the Health Belief Model (Janz & Becker, 1984). The hypothesized relationships in the study model (Figure 1) were drawn from studies indicating the effectiveness of multimodal educational interventions for infection prevention (Backman, Zoutman, & Marck, 2008; Boyce et al., 2002; McGuckin & Govednik, 2013; Hugo Sax et al., 2009).

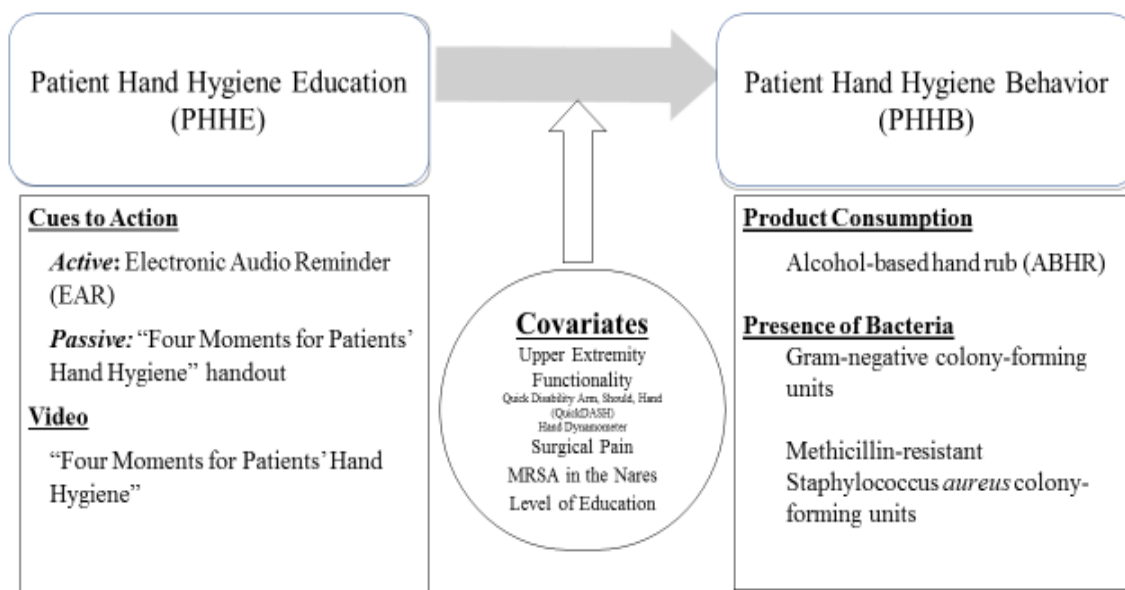


Figure 1 Patient Hand Hygiene Model

The overarching concepts used to guide this study are from the Nursing Metaparadigm: Person, Environment, Health, and Nursing. *Person* is the adult surgical-patient who has had non-emergent lower extremity surgery; the *environment* is the hospital in the post-surgical care environment. *Nursing* provides the educational intervention (electronic reminder, handout video, and handout) about patient hand hygiene behavior, and the *individual adaptation* is the patient's practice of hand hygiene. While there are very few theories identified to explain the phenomena of interest; the phenomena of interest can be postulated from the relationships of components from multiple theories. Researchers and health practitioners routinely use behavior change models to promote or improve patients' healthy behaviors. In addition to considering patient beliefs, attitudes and intention (Janz & Becker, 1984) to guide the interventions, the models also frequently incorporate self-efficacy, the individual's confidence in their ability to meet a goal (Bandura, 1982; Hoffman, 2013); however, the concept of active "Cues to Action", defined as resources associated with the ease of performing a certain

task, has not been explicitly identified in health behavior change models. The model used for this study *The Patient Hand Hygiene Model* is derived from Henderson's Concept of Nursing (1978) and Heitkemper and Shaver's Human Response Model (HRM) (Heitkemper & Bond, 2003), and the Health Belief Model (HBM) (1952). Henderson's conceptual framework is based on patient needs and nurse duties. The most applicable need in this study is to "Keep the body clean and well-groomed and protect the integument." (Marriner-Tomey, 1986), p. 141) The most applicable nursing duty is to assist the individual, sick or well in the performance of activities that contribute to their health and or recovery and that the individual would perform the task unaided if the person had the strength and or knowledge to do so (Henderson, 1966). The Human Response Model is a middle-range theory used to define relationships (adaptation) between person and environment. The Human Response Model, developed at the University of Washington School of Nursing in the mid-1980s by Cowan, Cunningham, Gallucci, Heitkemper, Mitchell and Shaver (Heitkemper & Bond, 2003), is proposed as an organizing framework for potential or actual health-related problems to be viewed in a holistic and dynamic interactive perspective (Heitkemper & Bond, 2003; Mitchell, Gallucci, & Fought, 1991). The Health Belief Model (HBM) was first developed in the 1950's by researchers Hochbaum, Rosenstock, and Kegels who worked for the U.S. Public Health Service (Burns, 1992). It was originally created to predict and explain if and why an individual would or would not participate in preventive methods such as tuberculosis screenings; a major concern at the time (Gagné et al., 2010). Irwin M. Rosenstock did a modification of the HBM in 1966 and further developed the HBM with Becker in the 1970's and 80's (Burns, 1992). The original Health Belief Model consisted

of four constructs: perceived susceptibility, perceived severity, perceived barriers, and perceived benefits. The HBM was later modified to include *self-efficacy* and *cues to action* (Mikhail, 1981). The model was modified to include influencing factors that predict the chances that an individual would practice the recommended health action such as prevention (Janz & Becker, 1984). A health action such as hand hygiene has mediating and moderating factors that influence practice. Patient hand hygiene is a necessary practice to decrease the risk of infection in the hospital setting (Sunkesula et al., 2015).

When exploring patient hand hygiene, it is important to explore factors that may influence behavior such as resources, education and physical ability. Exploring *cues to action* such as an electronic audio reminder (EAR) and “Four Moments” handout can contribute to the likelihood of the patient performing hand hygiene. In this study *The Patient Hand Hygiene Model* provides the framework to test an intervention designed to improve an essential health behavior: patient hand hygiene. By incorporating patient hand hygiene education and behavior into a conceptual model, patients, healthcare workers, and visitors can further appreciate the role of patient hand hygiene and the model’s potential guidance in future research.

Theoretical Definitions of Terms. The Patient Hand Hygiene model’s two major concepts are the Patient Hand Hygiene Educational Intervention (Cues to Action) and Patient Hand Hygiene Behavior.

Patient Hand Hygiene Education (Intervention). Education is defined as knowledge and skills learned systematic processes. The concept of patient hand hygiene was defined using the “Patient’s Four Moments for Hand Hygiene,” which specifies hand hygiene practice events similar to the Five Moments of Hand Hygiene (Sax et al., 2007),

an internationally adopted performance guideline for health care staff. The Four Moments stipulates similar times that are crucial for patient hand hygiene: (1) mealtimes (2) exiting and re-entering the patient room (3) contact made with catheters, devices, or wounds, and (4) after use of the bathroom or elimination practices. For the intervention, all participants (both groups) will receive a one page single-sided handout (passive cue to action), “Patient’s Four Moments for Hand Hygiene” also known as the “Four Moments” (Appendix A) (Sunkesula et al., 2015).

The patient hand hygiene educational intervention is a form of *Health Education*, designed to help people improve their health by increasing their knowledge or influencing their attitude on a specific educational focus (Kumar & Preetha, 2012).

Patient Hand Hygiene Behavior (Outcome). *Patient hand hygiene* is a practice that encompasses the traditional process of hand cleansing with a soap-water wash or the decontamination of the hands using an alcohol-based hand rub (CDC, 2015). This was measured by the amount of alcohol-based hand rub used (per weight and volume of units (equivalent to number of liters) of product), an 8-oz push down bottle of Purell Gel (PURELL® Advanced Instant Hand Sanitizer, 3659-12, GOJO Industries, Akron OH). A comparison of colony forming units (CFU) found on participants’ hands throughout the study were examined. The CFU of bacteria studied are MRSA and Gram-negative bacteria. Using an experimental two-group design, this study investigated the effect of an electronic reminder on hand hygiene practices in patients who were ≤ 12 hours following surgery into the three days’ post-operative period following a non-emergent Lower Extremity (LE) surgery. Participants were randomly assigned to one of two groups:

education (handout and video) plus an electronic reminder or education (handout and video) only.

Research Questions and Hypotheses

- 1) *Do participants in Group 1 (EAR) have better rates of Patient Hand Hygiene Behavior (alcohol-based hand rub and colony forming units) than those in Group 2 (No EAR).*
- 2) *Controlling for 5 covariates (QuickDASH & Hand Grip Strength, Surgical Pain, MRSA of the nares, Level of Education) is the Electronic Audio Reminder (EAR) a predictor of product consumption (ABHR use)?*

H₁: The electronic audio reminder (EAR) group (active cue to action) will use more ABHR.

H₂: The electronic audio reminder (EAR) group will have lower levels of colony forming units (CFUs) of MRSA and Gram [-] bacteria on their hands.

Significance to Nursing and Healthcare

Although the prevailing theory of infection transmission in the 1800's was miasma, or "bad air," Florence Nightingale, a nursing pioneer, writer, and statistician, advocated for personal hygiene and a sanitary environment as essential elements for a healing environment (Gill & Gill, 2005). Thus, without an understanding of bacteriology, infectious agents or germ theory, Nightingale meticulously documented patients' symptoms and used the results to develop effective infection prevention strategies (McDonald, 2001). Nightingale's landmark statistical techniques applied to puerperal fever and deaths of soldiers from the Crimean War provided methods to explore healthcare-associated deaths due to a lack of personal hygiene (Gill & Gill, 2005). This helped to provide the foundation for hand hygiene programs initiated today (Fee & Garofalo, 2010). Hospital infection control programs continue to use these principles today.

If healthcare workers are known to spread pathogens from one site to another via unclean hands, patients can be capable of doing the same. Furthermore, the pathway and distinction between community-acquired infections and healthcare-associated infections remains in question (Henderson et al., 2014; Otter & French, 2011; Uhlemann, Otto, Lowy, & DeLeo, 2014) therefore, among other strategies, it is important to reinforce home hygiene habits for people who are admitted to the hospital.

Patient Education. The opportunity to educate and or remind patients of the importance of including hand hygiene in their self-care can help contribute to their safety. For example, the education and assistance that nurses and the staff provide to patients can potentially help patients prevent infection by breaking the cycle of infection transmission. Furthermore, the multimodal approach to hand hygiene including the patient's practice can increase the patient's comfort with asking healthcare staff to practice. One study shows that patients are less likely to ask healthcare workers about cleaning their hands if they do not regularly practice hand hygiene at home (Barker et al., 2014). Studies also show that patients perceive staff to be busy and are not encouraged to clean their hands (Ardizzone et al., 2013; Burnett et al., 2008). Findings from this educational intervention study will provide evidence that helps nurses help patients self-manage their hand hygiene without an increase in healthcare worker workload. Patients feel comfortable speaking up and contributing to their safety when it is encouraged by healthcare staff (Entwistle et al., 2010).

Nursing Education. Infection control knowledge and practices are poor amongst healthcare students (Hinkin & Cutter, 2014; Ojulong, Mitonga, & Ipinge, 2013; Singh et al., 2011; Wu, Gardner, & Chang, 2009; Wu et al., 2013) and they are recommended for

improvement within the educational setting. This study could provide evidence to inform undergraduate students about the importance of addressing infection control from a patient-centered approach with one method being patient hand hygiene. For nursing students, hygiene is one of the major things learned during the fundamentals course, hand hygiene is a part of that equation. Students learning to incorporate patient hand hygiene into their practice could lead to it being a norm in the healthcare setting. A study examining students' knowledge and practice of infection control practices, specifically standard precautions suggests that improvement within education programs is recommended across all learning institutions prior to students transitioning into healthcare settings (Singh et al., 2011; Wu, Gardner, & Chang, 2009). For example, the study done by Wu et. al. (2009) found that of 175 nursing students provided with an educational intervention regarding infection-control practices, the students in the intervention group showed a statistically significant improvement [$F(2, 175) = 13.53, p < 0.001$] in comparison with the comparison group. Beginning infection control practices early a nurse's career can lead to effective changes within infection control programs.

Policies and Guidelines. Currently, governing entities and accrediting bodies with established mandates do not incorporate patient hand hygiene as a strategy for infection prevention. Studies similar to this one can guide the widespread formation and implementation of guidelines for patient hand hygiene as part of infection prevention policies. Without excluding the current infection prevention methods, this study provides the beginning steps of a comprehensive method for a patient-centered approach to infection prevention. The next steps in research following the results of this study is to refine and validate the educational intervention used amongst more diverse populations

including women and children and in different healthcare settings so that results can demonstrate generalizability. This is a foreseen limitation to this study.

Assumptions

The primary study assumption is that hand hygiene is the first line of defense in the prevention of infection and therefore, it is an important aspect of preventing healthcare-associated infections. A second assumption is that patient hand hygiene constitutes a learned behavior that hospitalized post-operative patients can learn, or re-learn, and successfully and independently incorporate into their personal hygiene.

Summary

Chapter 1 includes an introduction to the study of infection control measures and patient hand hygiene practices in the acute-care setting. The theoretical framework, concepts, research questions and assumptions for this study were also presented. Chapter 2 reviews pertinent literature on patient hand hygiene and principles related to the acute care setting. Chapter 3 explains the procedures used for data collection, measurement and the rationale for the data analysis, Chapter 4 presents results, 5 provides a discussion of the findings and includes information about limitations, implication of study findings, and next steps. The Appendices contain all of the study materials.

Chapter II

Literature Review

According to the Centers for Disease Control and Prevention (CDC) clean hands reduce the chance of a person becoming infected with disease(s). Hand hygiene is an essential behavior in the effort to decrease the spread of pathogens from person to person, object-to person, person-object, and or object-to-object (Ellingson et al., 2014). The behavior of hand hygiene has been studied in different settings such as schools, food manufacturing, and healthcare settings (Al-Tawfiq, Abed, Al-Yami, & Birrer, 2013; Barker et al., 2014; Gerald et al., 2012; Green et al., 2007). In the hospital setting, sanitary practices and safe health are vital to the productivity of healthcare staff and the well-being of the patients. Research shows that using sanitation methods, techniques, and protocols can help prevent health issues for healthcare workers, visitors and patients (Abbas & Armstrong, 2011; Ardizzzone et al., 2013; Birnbach et al., 2012; Gagné et al., 2010; Ottum et al., 2013; Reiner & Callaghan, 2013; Sunkesula, et al., 2015). While the Joint Commission (2009) and World Health Organization (2009) recognize the importance of patient participation in hand hygiene, both do so by instructing patients to remind healthcare staff to clean their hands. Neither organization specifically discusses patients' personal self-management of hand hygiene practices. Limited emphasis on independent hand hygiene practices of hospitalized patients, along with the continued prevalence of healthcare associated infections, indicates the need for more effective patient-focused strategies to increase hand hygiene and thus, minimize the spread of pathogens.

Hand Hygiene Theories

Hand hygiene is a self-management behavior. The Theory of Planned Behavior is commonly used in the acute care setting to understand the hand hygiene behavior of healthcare workers.

Theory of Planned Behavior. The Theory of Planned Behavior (TPB) is a decision-making model that has been used in different contexts, but in healthcare is commonly used to explain the “Five Moments for Hand Hygiene” of healthcare staff (O’Boyle, Henly, & Larson, 2001; White et al., 2015). The Theory of Planned Behavior is derived from two major theories: The Theory of Reasoned Action and Theory of Self-Efficacy. In 1975, Martin Fishbein & Icek Ajzen designed a theoretical model Theory of Reasoned Action (TRA) which was used to understand how behavior is centered on attitude (Beck & Ajzen, 1991). After Albert Bandura proposed the Theory of Self-Efficacy in 1977, the popularity and importance of it extended the TRA to not only include attitude as a construct, but also was extended to include control as a construct (Beck & Ajzen, 1991). In 1985, Ajzen expanded upon the Theory of Reasoned Action and created the Theory of Planned Behavior (TPB) (Beck & Ajzen, 1991). The TPB discusses behavioral intention in that a person’s intention of performing a given behavior is the best prediction of whether or not they will act on it (Ajzen 1985, 1988, 1991). There are six constructs used in this theory: Attitude towards an act or behavior, normative beliefs which is the belief about what value people expect us to do, and perceived behavioral control, which is the degree to which a person thinks they can control the behavior (Beck & Ajzen, 1991). The TPB concepts: intention, perceived control, control beliefs, subjective norm, normative beliefs, attitude about outcomes were

tested for internal consistency and found to have a range of Cronbach α ranging (.64-.89). However when healthcare workers were asked to report their practices and beliefs in hand hygiene the correlation between observation and self-report was low ($r=.21$) (O'Boyle et al., 2001). These findings are similar to another study that found that while 93% of patients reported hand hygiene was important, only 8% practiced prior to a patient hand hygiene intervention (Sunkesula et al., 2015).

The TPB relates to patient hand hygiene in multiple ways. For example, when examining the three components and sub-components as viewed in the model as they relate to the behavior of patient hand hygiene; patient's attitude towards the act of hand hygiene is important to understand. The normative beliefs are to what extent people expect patient hand hygiene to occur, and perceived behavioral control is the degree to which a patient can perform hand hygiene. However, it is well documented that education alone is not enough to change patient hand hygiene behavior. For example, multiple studies indicate that while patients understand the importance of hand hygiene they rarely practice in the acute care setting (Ardizzzone et al., 2013; Barker et al., 2014; Sunkesula et al., 2015).

Hand Hygiene Overview

Definition. Hygiene is defined as the maintenance or preservation of health ("hygiene - definition of hygiene by Medical dictionary," n.d.). Hand hygiene is defined as the single most effective method that prevents the spread of healthcare-associated infections. It is a practice that encompasses the traditional process of hand cleansing with a soap-water wash or the decontaminating of the hands using an alcohol-based hand rub (CDC, 2002). The importance of hand hygiene in hospital settings has been recognized as

an important topic since the early 1800's (Allegranzi & Pittet, 2009). The basic process of hand hygiene, as outlined and defined by the CDC (2002), has been, and continues to be, the basis for hospital infection control programs. According to the CDC hand hygiene is defined as a disinfecting process of the hands. For example, hand washing, antiseptic hand wash, antiseptic hand rub, or surgical hand antisepsis are considered as disinfecting processes (Boyce et al., 2002). *Patient hand hygiene* utilizes the same process as outlined by the CDC, but targets a specific group: the patient.

Regardless of the group, the indications for hand hygiene depend on the type, intensity, duration, and sequence of activities performed. CDC (2015) guidelines suggest that hand hygiene should be accomplished for a variety of contacts: before handling food, before and after touching wounds, before performing invasive procedures, and toileting. In light of today's emphasis on patient engagement and patient-centeredness, patient hand hygiene should be included as an important aspect of care in the acute-care setting.

Measurement. Direct observation, the gold standard for measurement of hand hygiene, provides Infection Preventionists with opportunities for coaching, teaching, and evaluating hand hygiene technique and practices, but its strengths for practice can become limitations for research, the most significant of which is the Hawthorne Effect: compliance rates are positively biased because the study participants know they are being observed. Labor intensity and the observer's subjectivity also can be a limitation to this type of measurement (Tejada & Bearman, 2015). Technology has provided the ability to measure hand hygiene compliance electronically through video surveillance systems. In comparison with other methods, these electronic systems provide reporting mechanisms and immediate feedback of healthcare worker hand hygiene. However, there are several

limitations including the inability of electronic surveillance to capture all of the moments when hand hygiene practice is necessary. The costs of these systems can be very expensive and the installation, technical, and power support also can be extensive (Tejada & Bearman, 2015). A third approach to measure hand hygiene is by the amount of product consumption. Hospitals have measured hand hygiene based on the amount of product purchased, the amount used, or even through the placement of electronic counting devices inside dispensers. This method avoids the Hawthorne Effect associated with observation, utilizes fewer resources, and has been successfully used to measure consumption. However, limitations are the inability to determine the users of the solution and/or the techniques and opportunities for hand hygiene (Tejada & Bearman, 2015). The advantages and disadvantages of different measurements for hand hygiene was discussed further as they provide justification for multi-modal strategies in infection control research.

Skin Flora and Pathogens

In one of the earliest papers on the bacteriology of normal skin, Price (1938) documented the existence of two types of skin flora, resident flora and transient flora. The first type, resident flora, is normal flora; it is fairly stable in numbers, attached to the skin, and relatively free of pathogens (germs that cause infection or disease). The second type, transient flora, often contains pathogens, varies considerably in magnitude, and is less well attached to the skin than normal flora (Price, 1938). It is this second type of flora that is the target of Infection Preventionists, as Price's series of experiments also conclusively demonstrated that mechanical cleansing techniques which included sustained friction (scrubbing), in addition to soap and water, effectively reduced transient

but not resident bacteria. Later experiments, such as those by Lowbury and colleagues (1964), supported the claim that friction was as important as the antiseptic agent in hand hygiene. Infection Preventionists continue to build on this body of work in the 21st century.

Relationships between Pathogens and Patients. Research that is more recent documents the multiple links of transient flora among patients, staff, and hospital environments as they pertain to hygiene, and in particular, hand hygiene. There are numerous shared environmental and skin contact points between patients and healthcare workers: person to person, object to person, person to object, and/or object to object (Ellingson et al., 2014). For example, patients are not restricted in their personal contact with other patients; they are in frequent contact with environmental surfaces such as bedside tables, bed rails, medical devices, or call lights; and/or they can self-contaminate via surgical wounds, healing and non-healing ulcerations, indwelling medical devices, and/or the mouth (Casewell & Phillips, 1977; Jury, Guerrero, Burant, Cadnum, & Donskey, 2011; E. Larson, 1988; Sethi, Al-Nassir, Nerandzic, Bobulsky, & Donskey, 2010).

Pathogens, Patients, and Healthcare Workers. There is evidence that the pathogenic organisms found on the hands of acute care patients are the same as those on healthcare workers (Larson, 1988); for example, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococci*, and *Clostridium difficile* have been found on the hands of healthcare workers (Sydnor & Perl, 2011) and patients (Istenes et al., 2013). Other studies have documented more direct links between patients and staff. In the United Kingdom, Casewell and Phillips (1977) measured *Klebsiella* species in the

intensive care unit. All seven patients in the study were found to have *Klebsiella* in the nasopharynx; most also had it on their skin. Six cases indicated that the germs were transferred from the patient's hands to the nurse during the time that the nurse was performing "clean" care. The serotypes of *Klebsiella* infecting or colonizing patients were identical to those of staff taken the same day. In 47 observations, nurses were found to transmit *Klebsiella* 17 times. Of the 17 instances, 7 patients were found to have *Klebsiella* located in the groin or on their hands (Casewell & Phillips, 1977). This early study provided convincing data linking patients and staff to one particular pathogen.

Fifteen years later, Sanderson and Weissler (1992) documented the presence of coliforms on the hands of nurses and the hands and other body parts of patients and the types of nurse activities that could lead to cross-contamination between nurses and inpatients in a United Kingdom orthopedic hospital. Using a pre-post design, the finger pads of nurses and patients were disinfected and then cultured before and after nurse activities for patient care (Sanderson & Weissler, 1992). Post cultures showed coliforms on both the hands of nurses and their patients, with a greater number of coliforms on patient cultures. Conducted in an orthopedic hospital, patients also were most likely to have coliforms in the perineal area. For nurses, the highest rates of contamination on their hands were found after nurses handled patients' items related to bathing, followed by bed making and touching the patient or their clothing. An unexpected finding was that there also was contamination during medication administration activities. The authors concluded that the sources that contaminated nurses' hands were the same materials that were a direct source from the patients. The study only examined coliforms and was

limited by sample size (N=20 patients); however, the results indicate the close links among pathogens, patients, and nurses (Sanderson & Weissler, 1992).

A more recent study in the United States, conducted on a medical/surgical unit in an urban hospital, focused only on patients, documenting evidence of pathogens on their hands (Istenes et al., 2013). A convenience sample of 100 patients participated and provided 100 samples (1 dominant hand sample per patient) using the American Society of Testing Methods (ASTM) E 1115-10, also known as the “glove juice” method. The method had 92% accuracy rate for this study (Istenes et al., 2013). Of the 100 patients, 39 (39%) tested positive for at least one pathogenic marker organism and 8 patients tested positive for 2 or more pathogenic organisms. Pathogens detected were *Acinetobacter* (11 patients), MRSA (14 patients), *Clostridium difficile* (14 patients), and vancomycin-resistant *Enterococci* (9 patients). The results indicated significantly different rates of hand contamination based on mobility in that patients who needed assistance to ambulate to the sink had higher positive hand cultures than patients requiring minimal assistance. Of importance, 25 patients were diagnosed with an infection, but only one of the infections was hospital-acquired. The remaining 24 patients were identified as carriers of pathogens at the time of admission (Istenes et al., 2013), which raises the concern for pathogens entering the acute care setting via patients from the community.

Pathogen Counts: Inpatients Comparable to Outpatients. General ward inpatients are not the only patients who carry pathogens. In her large descriptive study, Larson (2000) found that patients in the outpatient setting and patients in the intensive care unit carry pathogens on their skin. Contact plates were used to sample the forearms and mid-sternums of participants in both groups (n=251 in each group). Patients in the medical

intensive care unit were significantly more likely (OR, 2.48; [95% CI: 1.34-4.43]; $p = .004$), to carry more colony-forming units on their arms than patients in the outpatient setting (Larson et al., 2000). MRSA notably was not different in prevalence between inpatient and outpatient groups; however, a significant number of various pathogens were identified for both the inpatient and outpatient groups.

Patients/Residents that receive care external to the acute care setting for example in nursing homes and skilled nursing facilities are considered to be a part of the community. The relationship between pathogens found in nursing homes and long-term care facilities and their relationship to acute care settings is an emerging topic in addition to infection control issues amongst older adults (Mody, 2007). A study showed that 24.1% of older adults ($n=357$) admitted from the hospital to several assisted-living facilities in south east Michigan tested positive for at least one multi-resistant drug organism (MRDO) and that patients the high levels of MRDOs discovered on patients' hand increases the chance of these superbugs being transmitted to healthcare workers and other frail patients (Mody et al., 2015).

Pathogens: Patient-Acquired from the Community. A final issue related to cross-transmission (people-to-people or people-to-object) is the issue of organisms entering the hospital setting from the outside environment. Emergency departments (EDs) are a major entry point for pathogens that may come from the community setting because they specialize in the treatment of patients who present with a broad range of acute illnesses. For example, in a recent study of the amount of isolated bacteria acquired from cultures of ED patients compared to hospitalized patients, pathogens from the community setting were as serious a factor as pathogens acquired from the hospital

setting (Draper, Farland, Heidel, May, & Suda, 2013). Draper's study was conducted in a 335-bed community hospital in a suburban area; the ED averaged 55,000 visits/per year, yielding an 80% admission rate from patients initially treated in the ED. The 13-month study abstracted data from microbiology laboratory reports comprised of all bacterial cultures obtained in the hospital, with each culture coded by the location in which the culture was collected. Of the 3,140 cultures between ED patients and hospital patients, 1,417 were from ED patients and 1,723 from inpatients. Forty percent of the ED cultures grew six different gram-positive pathogens and 60% of the cultures had 12 different gram-negative pathogens (Draper et al., 2013). Pathogens such as MRSA (a common HAI) had similar frequencies to ED patients (75.1% and 75.4%, respectively); however, gram-negative pathogens were isolated more frequently in ED patients (59.7%) than hospitalized patients (47.8%; (Draper et al., 2013).

In discussing these findings, Draper and colleagues noted that the lack of accurate rapid diagnostic tests for ED patients increases the risk of pathogens being transmitted into the inpatient setting once patients are admitted. This can pose a risk to compromised patients who are acutely ill and have comorbid conditions and thus are susceptible to deleterious outcomes from HAIs (healthcare-associated infections). Hands are one of the major contamination sources that lead to HAIs, therefore, programs supporting hand hygiene for ED patients can decrease the risk of infection for these and other hospital patients, whether the ED patients transition to the inpatient setting or are sent home. The hope is that, either way, they will not enter the acute care setting acquiring an HAI or going home and acquiring a community-acquired infection. In exploring patient hand

hygiene as a method of preventing HAIs, it is important to understand the patient's current behaviors.

Measurement of Patient Hand Hygiene Behavior

Observation Studies. Observation is considered the “gold standard” for the measurement of hand hygiene behavior. In one of the earliest studies of patient hand hygiene, Lawrence (1983) reported that 12 of 20 patients (60%) observed in an acute care setting didn't clean their hands after using a bedpan or commode. Following the patient hand hygiene observations, patients were asked to complete a survey. According to the survey results, 10% of patients were offered assistance with performing hand hygiene after toileting. However 95% of patients indicated on the same survey that they clean their hands after toileting at home (Lawrence, 1983). The survey results also reported that the patients' major reason for not practicing hand hygiene in the hospital was that while they needed help (cleansing their hands), they perceived that the staff was too busy to help them with this task.

Twenty-five years after the Lawrence study, Burnett, Kydd, and Lee (2008) conducted a small mixed methods pilot study on six wards (two medical, two surgical, and two orthopedic) in an acute care teaching hospital in Scotland. Per clinical evaluation, all patient participants (N=22) required assistance with hand hygiene. In the first part of this study, six 4-hour observation sessions (7:30 a.m.-11:30 a.m.), conducted by infection control nurses, recorded type and frequency of all behaviors in which nursing staff offered the patient participants help and/or facilitates with patient hand hygiene.

Immediately after the observational sessions, nursing staff associated with the care of the patient participants were given the opportunity to complete a 10-item questionnaire. Simultaneously, the patient participants completed a semi-structured interview with the researcher. In both the nurse surveys and patient participant interviews, perceptions of patients about hand hygiene were obtained. Patient hand hygiene was reported as an important practice for preventing or controlling the spread of HAIs by 100% of the nursing staff and 95% of patients (Burnett, Lee, & Kydd, 2008). Nurses reported offering patients hand hygiene resources 64% of the time. Conversely, patients reported that they were offered hand hygiene resources 14% of the time during the same observation period. Findings indicated that while nurses and patients believe that hand hygiene is important, unless patients are able to perform hand hygiene independently, they are rarely offered the resources or encouraged to do so. Patients also did not ask healthcare staff to assist them or failed to do it on their own. A common reason mentioned by patients was that they did not feel that their hand hygiene was important enough to disturb the staff (E. Burnett et al., 2008). In a second study, Burnett (2009) reported similar findings about nurse attitudes, with 442 nurses (99.8%) reporting that patient hand hygiene practice was important.

Product Consumption. Given the limitations of observation, other methods have been used to measure patient hand hygiene. Savage and colleagues (2011) used the World Health Organization (WHO) “Five Moments of Hand Hygiene” and two of WHO’s recommended approaches to measure the hand hygiene practices of healthcare workers, visitors, and patients of 27 wards in 9 acute National Health Service Trusts: (1) product consumption of alcohol hand rub at ward entrances, and (2) 36 hours of direct,

unobtrusive observations at the bedside (Savage et al., 2011). The alcohol-based hand rub containers at 10 ward entrances were monitored and use was recorded in liters. Old containers were replaced with new containers daily. In analyzing the results, the average daily volume of solution (from previous 12 months) was compared with the average daily amount used during the two-month study. The study was conducted at consistent times (1 p.m.-8 p.m.) during the months of January and February (Savage et al., 2011). All wards had notices at their entrances requesting hand hygiene and all had wall-mounted alcohol hand rub dispensers. Direct bedside observations were made during peak visiting hours. For observation data, a researcher used tally marks to count each hand hygiene event. In examining the use of either bedside soap or alcohol-based hand rub at the bedside, patients (n=151) did not use either, 4% was used by visitors (n=121) and healthcare workers (n=175) were the overwhelming consumers, accounting for approximately 96% use of both products (Savage et al., 2011).

Self-Report. A third way to measure patient hand hygiene behavior is through self-report. A recent cross-sectional study done at a Veterans Affairs Hospital found that patients reported different rates of hand hygiene practices between hospital and home (Barker et al., 2014). Using the CDC standards for hand washing, an interview-administered survey was developed and implemented. The sample included 207 patients (98.6% response rate). Patients reported that they were comfortable asking for their hands to be cleaned by healthcare workers before eating and after restroom use; however, findings also indicated that rates of hand cleansing before eating or after restroom use were less in the hospital than at home (Barker et al., 2014). Compared to home, patients reported that hand hygiene reported after restroom use was 14.5% less likely, $\chi^2 (2, 207)$

= 14.5, $p < .001$. The poorest rates of hand hygiene at mealtime were associated with older age and decreased mobility, $\chi^2 (2, 207) = 19.1$, $p < 0.006$ and $\chi^2 (2, 207) = 14.6$, $p < 0.03$, respectively. Similar to previous studies, several factors contributed to the patient's level of comfort in asking for or utilizing help from healthcare workers to practice hand hygiene (Barker et al., 2014). For example, good hand hygiene practices by patients at home before eating was one of the factors associated with patients feeling comfortable asking healthcare workers for help. Of importance, Barker's study also notes that all 207 study participants had hand wipes on the meal trays as part of usual care, which raises the question of whether placing the wipes on the tray is enough, or if a reminder could increase patient hand hygiene practices before meals (Barker et al., 2014).

Electronic Monitoring. In a recent cross-sectional study, Canadian researchers used an established ultrasound-based Real-Time Location System (RTLS) to examine the patient hand hygiene behaviors in three multi-organ transplant units over 13 months (Srigley et al., 2014). The RTLS gauges hand hygiene events by the interaction of the system's radio frequency identification (RFID) tags and the location of the transponders that the patients wear. Prior to the study, reliability and validity of the RTLS was established using a series of clinical simulations in both single and double rooms for patients, including the bathrooms (Srigley et al., 2014). The detection of hand hygiene moments for staff showed a positive predictor value of 97.4% when tested for sensitivity and specificity. Of the 1,132 patients admitted to the units during the 13-month study period, 279 (24.6%) agreed to wear transponders. Patient participants were blinded by being told that the ultrasound transponders were being used to monitor staff-patient interactions. Four times were used as measurement criteria for when patient participants

should clean their hands: during visits to bathrooms, mealtimes, kitchen visits, and when entering and leaving their rooms. Mealtimes included a 90-minute window three times per day when meal trays would be delivered to the patients (Srigley et al., 2014). Patients were measured by the transponder if they came in contact with the hand hygiene dispensers or soap and water by a sink during that time period. Overall patients had poor hand hygiene practices as detected by the RTLS: 29.7% of the time during bathroom visits, 39.1% during mealtimes, 3.3% when visiting the kitchen, 6.7% of the time leaving their rooms, and 2.9% of the time returning to their rooms. Findings indicated that hand hygiene is more likely among women (odds ratio, 1.77 [95% (CI), 1.64–1.91], $p < .001$) and for mealtimes, rates were the highest during dinner (45.9%) and breakfast (32.2%; (Srigley et al., 2014). There were no significant predictors of patient hand hygiene during mealtimes based on accessibility of resources. Compared to previous studies, this study had the largest sample and it avoided the Hawthorne effect. However, it was difficult to identify patient hand hygiene practice. In addition, patient hand hygiene was trackable in only specified locations tagged with the RTLS technology. Because the measurement of patient hand hygiene is poor as demonstrated by the aforementioned studies, this warrants attention to whether patients are knowledgeable about patient hand hygiene and argues for its greater practice in healthcare settings.

Patient Knowledge About Hand Hygiene and Healthcare-Associated Infections

Multiple studies have been done to measure the patient's perception about the importance of patient hand hygiene; however, very few gauge the patient's knowledge about HAIs (healthcare-associated infections). In a study measuring patient knowledge of HAIs, specifically MRSA and *Clostridium difficile*, 60 patients were surveyed and it was

found that 60% of them had no knowledge about these multidrug-resistant organisms (Abbas & Armstrong, 2011). From the sample of 60 participants, 78% did not know what “being in isolation” meant or if they were in any type of isolation (Abbas & Armstrong, 2011). The findings resulted in education being provided to patients and visitors about *healthcare worker* hand hygiene, but not about *patient* hand hygiene.

A recent study exploring patient knowledge of proper hygiene found that patients did not know or understand the difference between soap and water and alcohol-based hand rub (Busby, Kennedy, Davis, Thompson, & Jones, 2015). While this study did not focus on proper hand hygiene in relation to patient hand hygiene, the need for education about hand hygiene and products for use can have a relationship with deficient knowledge about self-practice (Busby et al., 2015; Gudnadottir et al., 2013).

A descriptive study using a surveying method examined patient preferences for educational material regarding HAIs (Gudnadottir et al., 2013). The study reported that of 200 patients with multidrug-resistant organism-related HAIs, 80% of the patients received written education materials about preventing HAIs at some point during their lifetime. Forty-nine percent of the patients reported being educated about HAIs via radio, video, and/or television. Twenty percent of the patients used the Internet to obtain information about preventing infections and 20% reported receiving education about infection prevention in academic settings (Gudnadottir et al., 2013). The majority (88%) of the patients reported that they received information on hand washing. Nearly all (98%) of the patients surveyed assumed that learning about HAIs was important, and 94% of those patients mentioned that obtaining information about multidrug-resistant organisms could help them make better decisions regarding their care. It was found that patient

educational learning preferences varied, with patients showing a preference for educational materials being multi-modal combinations of written and visual materials. Seventy percent of the patients preferred written material (53% a brochure, 46% a handout, and 23% a poster), 57% preferred verbal, 53% preferred an informational video, and 50% preferred information from the Internet. Patient preferences also differed depending on the patient's educational level and for whom they would prefer to obtain the information from. While 88% of the patients received education on hand washing, it was not inclusive of patient hand hygiene practice (Gudnadottir et al., 2013).

Educational Strategies. Education and training frequently are cited as effective methods for developing and maintaining hand hygiene compliance among healthcare workers (Pfoh, Dy, & Engineer, 2013). Hand hygiene is a learned behavior from childhood, therefore, providing education to renew and/or reinforce patient hand hygiene practice in the adult also can be effective. Hand hygiene educational interventions are effective for increasing and sustaining hand hygiene compliance at all ages (Gould & Drey, 2013). Huis (2012) and colleagues found that there are five determinants for hand hygiene that lead to behavior change. Of 41 studies reviewed, the most common determinants identified were *knowledge, awareness, action, control, and cue of the behavior*.

Patient Hand Hygiene Education Intervention Studies

Less common, but of great importance, are the patient-focused educational intervention studies that have been conducted to improve patient hand hygiene practice. It is commonly known that patient knowledge does not always translate into behavior change, but often requires a multi-modal approach.

Patient Education Interventions. Sunkesula and colleagues (2015)

demonstrated that while 94% of patients were found to be knowledgeable about practicing hand hygiene, initially only 6% practiced the hygiene (measured through direct observation) pre-intervention (Sunkesula et al., 2015). Sunkesula et al. (2015) used a multistage investigative approach—information about healthcare workers and patients’ knowledge of hand hygiene and trigger events when patients should practice hand hygiene—to design and test a patient educational handout, “Patient’s Four Moments for Hand Hygiene (Four Moments).” The four moments are (1) mealtime, (2) exiting and re-entering patient rooms, (3) contact with catheters, devices, or wounds, and (4) after use of the bathroom. To assess whether the patients’ practice of hand hygiene was congruent with their opinion of hand hygiene, preliminary survey data, using the handout and visual observations, were conducted during an 8-week period in the same hospital wards (Sunkesula et al., 2015). Survey results indicated that while 94% of the patients felt that hand hygiene is important, only 6% were observed practicing during the “Four Moments”. Observations also showed that patients had difficulty opening the wipes (given as a part of usual care) during their meal time. A facilitated patient hand hygiene intervention based on the “Four Moments” handout was conducted during a 1-month period in a 36-bed surgical ward. During the delivery of patients’ food trays, food service workers provided the patients with a sanitary hand wipe from a canister while asking the patients to clean their hands before eating. This intervention was associated with a significant increase in patient hand hygiene performance, increasing from 8% to 79% (448 of 569 observations) before meals, and from 0 to 51% (100 of 197 observations) when exiting or entering patient rooms (Sunkesula, et al., 2015). Providing ready-to-use

wipes placed directly on top of the food tray made it easy for patients to perform hand hygiene.

Another study examined the effectiveness of soap and water and alcohol-based hand rub for the removal of bacterial spores in the hand hygiene of patients who had been infected (n=28) or colonized (n=16) with *Clostridium difficile* (Kundrapu, Sunkesula, Jury, Deshpande, & Donskey, 2014). In a randomized trial comparing the effectiveness of two types of spore removal as measured by quantified colony-forming units (CFUs), swabs were collected from whole hands before and after the patients washed their hands or used hand rub. The sample size was 44; each patient had 2-4 hand hygiene assessments for a total of 121 hand cultures (60 hand washes and 61 alcohol-based hand rubs). Before the patients cleaned their hands, 15 (34%) of the hand cultures tested positive, with an average of 15 *Clostridium difficile* CFUs (range of 1-100). After hand washing, the *Clostridium difficile* was reduced to an average of only 2 CFUs. ((Kundrapu et al., 2014). Hand cleansing using alcohol-based hand rub demonstrated no significant difference in CFUs before and after use (14 CFUs and 13 CFUs, respectively); thus, it was concluded in this trial that alcohol hand rub was ineffective for *Clostridium difficile* spore removal, a finding confirmed in previous work (Jabbar et al., 2010; Oughton, Loo, Dendukuri, Fenn, & Libman, 2009). Kundrapu and colleagues (2014) found that 29 patients (73%) were unaware that alcohol-based hand rubs are ineffective in removing *Clostridium difficile* spores. Based on the CDC Hand Hygiene Guidelines, patients were educated on the appropriate method for hand washing.

Similar to Kundrapu and colleagues (2014), a quasi-experimental study conducted in acute care and utilizing similar methods (Sunkesula, Kundrapu, Macinga, & Donskey,

2015) focused on the reduction of MRSA. Of the 188 patients admitted to a VA medical center (acute care or long term care) who tested positive for MRSA, 82 (44%) qualified for the study due to exclusion/inclusion criteria. Of the 82 MRSA carriers enrolled, 67 (82%) had positive hand cultures. The intervention involved the one-time use of 2 milliliters of alcohol gel. Patients rubbed their hands with friction for 30 seconds while being coached on proper hand technique. One culture per subject was collected for sampling. To obtain the culture samples, a pre-moistened culture swab was rubbed across the surface of each hand (1 swab used for each hand). The colony-forming units of MRSA recovered, compared before and after hand hygiene, indicated that a single application of alcohol significantly reduced the percentage of positive cultures by 82%, $\chi^2(2, 82) = 5, p < .0001$, with 67 patients showing a significant reduction in MRSA CFUs. While the alcohol gel reduced the amount of MRSA on hands, patients that carried a high level of MRSA prior to the use of alcohol gel still had traces left on their hands (Sunkesula, Kundrapu, Macinga, & Donskey, 2015). Negative cultures were more common in carriers currently receiving antibiotics with activity against MRSA $\chi^2(82), 47, p = .04$. Devices or wounds or decreased mobility was not associated with hand contamination. Of 82 subjects, 56% were aware of the effect of alcohol against MRSA, with only 26% of them using it to clean their hands. Based on the CDC Hand Hygiene Guidelines, all participants were educated on the appropriate method for hand hygiene.

Sunkesula and colleagues (2017), used the “Four Moments” model for a randomized-control trial examining a patient hand hygiene intervention versus standard of care for a convenience sample of patients (n=95) from four medical-surgical wards with a minimal expected length of stay of two days. The intervention provided daily education and re-

education using a picture of the “Four Moments” model to teach patients about hand hygiene and a bottle of hand sanitizer. Patients were directly facilitated by data collectors to clean their hands after the collection of hand cultures. The control group received no education. Pre-moistened culture swabs were used to culture patients’ hands and their environment via bedrails upon admission and hospital days 2,4,5 to detect pathogens. Overall, 34% (16 of 47) control patients had pathogens detected on days greater than 1 from their hands in comparison with 1 of 44 intervention patients (2%) that had pathogens recovered from theirs. 14 control patients had a MRSA detected pathogen of which 13 (93%) had positive environmental cultures. One patient had MRSA detected in the environment, but was negative for hand contamination (Sunkesula, Kundrapu, Knighton, Cadnum, & Donskey, 2017).

Healthcare Worker Education Interventions. In a 1-year system, wide educational intervention conducted in Canada, Gagne, Bedard, and Maziade (2010) used four full-time and four part-time staff members to educate patients and family members how to properly perform hand hygiene and the importance of patient hand hygiene. After the educational intervention and assisting patients with cleansing their hands, hospital-acquired cases of MRSA dropped, from 10.6 cases to 5.2 cases per 1,000 admissions (Gagné et al., 2010). Specifically, MRSA surgical site infections went down 11%, MRSA bone/soft tissue infections went down 44%, MRSA urinary tract infection rates fell 18%, and MRSA septicemias fell 85%. Of importance, the overall mortality rate from MRSA-induced infections fell 71%. The benefit came economically as well. The entire project cost around \$170,000, but the net savings was estimated at \$688,843 in Canadian dollars (Gagné et al., 2010).

Nurse Ardizzone and colleagues (2013) explored the knowledge and perception of nurses (n=42) and patients (n=72) and concurrently conducted observations to compare survey results with what was actually occurring. Following the initial results from the survey, nurses were educated about patient hand hygiene and received feedback from the initial patient hand hygiene results. Nurses were educated on helping patients to clean their hands (Ardizzone et al., 2013). Postintervention, 55% of the patients reported they were never offered the opportunity to clean their hands. In contrast, 60% of the nurses said they did offer assistance with patient hand hygiene. The intervention resulted in an increase in staff-assisted hand hygiene opportunities, with observations increasing from 14 of 81 (17.3%) observed to 37 of 83 (44.6%) observed (Ardizzone et al., 2013).

Education Interventions for HCWs and Patients. In Hong Kong, an experimental study was conducted using an educational approach to patient hand hygiene in which the differences between self-initiated and staff-initiated patient hand hygiene of 582 conscious patients were examined for approximately six months (Cheng et al., 2016). Patients observed were from medical (41%), surgical (23%), orthopedic (21%), and obstetrics/gynecology (15%) wards, with a small sample (4%) from residential care homes. It was found that patients from residential care homes had significantly lower self-initiated hand hygiene practice ($p=.007$) in comparison with acute care patients ($p=.023$). In Cheng et al.'s (2016) study, despite an educational campaign using the "Four Moments of Patient Hand Hygiene" (Sunkesula et al., 2015) showing the important times to practice hand cleansing, and alcohol-based hand rub being provided to patients, staff-initiated patient hand hygiene was significantly higher (97.3%, 428/440) in comparison to self-initiated patient hand hygiene (37.5%, 218/582; $p < .001$). Patient hand hygiene

compliance was similar to the historic rate of healthcare workers' hand hygiene compliance (<40%). Regardless of age, hand hygiene was poor during important times when patients should practice it (Cheng et al., 2016). While facilitated patient hand hygiene is a suggestive approach, healthcare worker burden should be considered.

Patient Product Preference and Feasibility

To date, there is only one study (Tanner & Mistry, 2011) that examines patient satisfaction with and preference of hand hygiene products with consideration given to mobility, age, dexterity, and vision. The preference results showed that out of a sample of 200 patients, 77 (45%) preferred alcohol foam, 29 (17%) a mobile sink, 28 (15%) an alcohol wipe, 26 (15%) a wet antiseptic cloth, and 10 (6%) preferred a bowl of soapy water. Thirty-four adults age 60 and older struggled to open individual hand wipes (Tanner & Mistry, 2011).

A study assessed the ability for a convenience sample of 42 hospitalized patients and 46 long-term care facility (LTCF) residents to use three hand sanitizer products (8-ounce pushdown pump bottle, a 2-ounce pocket-sized bottle with a re-closable lid, and a pack of alcohol-impregnated hand wipes). The time (seconds) required for accessing each product was compared among acute-care patients and LTCF residents. Participants provided feedback on which product they preferred and found easiest to use. Of 88 participants, 86 (97.7%) preferred the pushdown pump, 2 (2.3%) preferred the bottle with the re-closable lid, and none preferred the hand wipes. For both hospitalized patients and LTCF residents, the average time required to access the pushdown pump was significantly less than the time required to access the other products (pushdown pump, 0.45 seconds; bottle with re-closable lid, 3.86 seconds; wipes, 5.66 seconds; $P<.001$).

Feasibility and ease of use should be a consideration in selecting hand hygiene products for patients to clean their hands while receiving care (Knighton et al., 2017).

Cue Reminders

A study conducted by Rai and colleagues (2017) hypothesized that patients might be willing to perform hand hygiene upon entry of healthcare workers entering their room as a nonverbal reminder of the importance of hand hygiene. In this model, a fifth moment was added as a way to increase patient hand hygiene. this fifth moment to To determine the impact of the intervention patient hand sanitizer bottles were weighed each afternoon for 3 days. Direct observation of personnel exiting and entering the patients room was the time of data collection. For 43 baseline observations, only 1 patient (2%) performed hand hygiene upon healthcare worker entry into the patient's room. Of the 43 patients, only 3 (7%) had an unsealed bottle of hand sanitizer visible at the bedside. Fifty-four patients agreed to participate in the hand hygiene study, 28 (52%) were randomized to the intervention group and 26 (48%) to the control group. Of the 28 intervention patients, 12 (43%) stated they would "definitely" be willing to model hand hygiene for providers, and 16 (57%) stated that they would be "somewhat" willing to model hand hygiene for providers. A total of 342 hand hygiene observations were done, 160 were in the intervention group and 182 were in the control group. Results showed statistical significance on day 1 and decreased as days passed. The intervention group used significantly more hand sanitizer gel than the control group. The percentage of patients clean their hands was greater in the intervention group (75% [21/28] vs 19% [5/26], respectively; $p = .0001$ (Rai et al., 2017).

Conclusion

Studies around the globe indicate that patient hand hygiene research is important and has international implications. This integrated review demonstrates limited research, however there are now compelling reasons to move beyond healthcare worker hand hygiene programs and focus on patient hand hygiene interventions designed to improve hand cleansing practices and decrease cross-contamination and the transmission of pathogens (FitzGerald, Moore, & Wilson, 2013). Furthermore, studies early as 1977 demonstrate that although patients and healthcare workers had pathogens on their hands, the conclusions and discussions only focused on strategies for improving healthcare worker hand hygiene practice. Patients can carry pathogens on their hands and therefore should *not* be regarded as only monitors of healthcare workers' hand hygiene, but as active participants in practicing personal hand hygiene. There are many instances in the healthcare setting in which patients should cleanse their hands. The next steps in this area of research should be focused on interventions aimed patient-centered hand hygiene and how it can be incorporated into existing infection control programs. The potential implications of effective patient hand hygiene include significant decreases in HAIs caused by the spread of dangerous and sometimes deadly pathogens such as multidrug-resistant organisms, and the reduced incidence of patients bringing such pathogens into and contaminating the healthcare environment. Other considerations that may result from better patient hand hygiene include improved patient satisfaction, treatment cost savings, and reduced length of hospitalizations.

Chapter III

The purpose of this 2-group comparison study tested the effectiveness of two educational-based approaches to improve patient hand hygiene in older veterans hospitalized for elective lower extremity orthopedic or podiatry surgery. Group 1 received an educational video, an educational handout, the ‘Four Moments’ handout, and an electronic audio reminder (EAR), that reminded the participant to clean their hands three times during wake hours with alcohol based hand rub (ABHR). Group 2 received only the educational video and ‘Four Moments’ handout. The Patient Hand Hygiene Model (Figure 1) was used to guide this study.

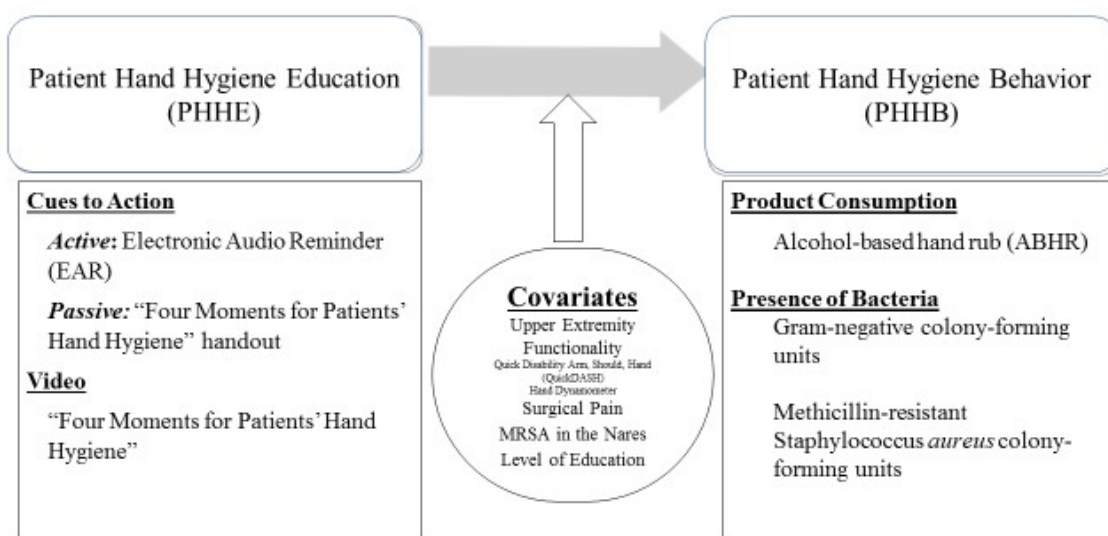


Figure 1 Repeat from Chapter 1 Patient Hand Hygiene Model

A description of the study sample is provided in this chapter followed by the results according to the research questions answered. A comparative effectiveness design utilizing several methods of data collection and multivariate analyses was used to answer the following research questions:

A 2-group experimental design utilizing multiple methods of data collection and multivariate analyses was to answer the following research question(s):

- 1) *Do participants in Group 1 (EAR) have better rates of Patient Hand Hygiene Behavior (alcohol-based hand rub and colony forming units) than those in Group 2 (No EAR).*
- 2) *Controlling for 5 covariates (QuickDASH & Hand Grip Strength, Surgical Pain, MRSA of the nares, Level of Education) is the Electronic Audio Reminder (EAR) a predictor of product consumption (ABHR use)?*

H₁: The electronic audio reminder (EAR) group (active cue to action) will use more ABHR.

H₂: The electronic audio reminder (EAR) group will have lower levels of colony forming units (CFUs) of MRSA and Gram [-] bacteria on their hands.

Operationalization of Terms

In this study, the patient and nurse (principal investigator) participate in a systematized teaching-learning process using a protocol. In this study, the patient, principal investigator and or research assistant participate in a systematized teaching-learning process that includes a reminder an active *cue to action* (Electronic Audio Reminder (EAR) and a patient hand hygiene handout a passive *cue to action*. A second educational component is a reminder. reminder is someone or something that triggers another person to remember something and/or assists them with achieving a task or goal (“Reminder | Define Reminder at Dictionary.com,” n.d.). In this study *cues to action* are the Four “Moments” handout and the EAR. The handout was to reinforce the “Four Moments” educational video shown to the comparison group. The electronic audio reminder (EAR) and handout was used to reinforce the “Four Moments” educational video shown to the intervention group.

This study contains an independent variable, dependent variable and four covariates. The concepts and operationalization of terms involved in this study are briefly explained below and presented in Table 1 followed by background information for some of the

major concepts and covariates considered for this study. *Patient hand hygiene education* (intervention) and *Patient hand hygiene behavior* (outcome) was measured by ABHR product consumption (per weight of the container using a scientifically calibrated electronic digital scale) with a secondary measure of bacterial presence (CFUs as measured by hand swab cultures). Of the five covariates, *upper extremity functionality* (as measured by The Disabilities of the Arm, Shoulder, and Hand Score (QuickDASH) and Hand Grip Strength (hand dynamometer), were used as indicators of the ability for participants to perform hand hygiene, an essential activity of daily living. The QuickDASH is a 11-item questionnaire that asks about patients' symptoms as well as their ability to perform certain activities within the past week. The questions focus on difficulty and pain involving the shoulder, arm, and hands. Every question is based on the patient's condition, the week before they came into surgery.

Table 1 Study Concepts, Variables, and Instrumentation

Study Concepts, Variables and Instrumentation			Data Collection
Intervention:	Patient Hand Hygiene Education:		
Electronic Audio Reminder (EAR)	<ul style="list-style-type: none"> • EAR (Return Demonstration) Participant Receive Reminder=1, No Reminder=0 		Quality check every 24hrs
'Four Moments' Video	<ul style="list-style-type: none"> • Return Demonstration 		Post-operative Day (POD) POD 0
'Four Moments' Handout	<ul style="list-style-type: none"> • Handout left on participants' bedside table 		POD 0
Outcome:	Patient Hand Hygiene Behavior:		
Product Consumption	<ul style="list-style-type: none"> • Alcohol-based hand rub (ABHR) consumption measured by weight (grams) / electronic digital scale 		POD 0-3 (every 24hrs)
Presence of Bacteria	<ul style="list-style-type: none"> • Hand Swab Cultures/Colony Forming Units (CFUs) 		POD 0 & 3
Covariates:			
	Upper Extremity Functionality	1. Quick Disability Arm, Shoulder, Hand (QuickDASH) No Difficulty to Severe (0-100)	POD 0 POD 0
		2. Hand Strength: Dynamometer/Kilograms	
	Surgical Pain	Computerized Patient Record System (CPRS)/ Daily Average from Day/ Evening /Night Nurse Assessment Notes (0-10)	POD 0-3
	MRSA of the Nares	CPRS (1= Positive, 0=Negative)	POD 0-3
	Attitude & Behavior	At Home: 1. How much do you value clean hands? (Likert Scale- Not Important=0 to Very Important=5) 2. How often do you clean your hands at home daily? By clean, I mean wash your hands or use hand sanitizer? 0=rarely (0-1 time) to 3=often (>5 times)	POD 0
	Level of Education	Highest Level of Education Attended (4=College, 3=High School, 2=Middle School, 1=Grade School)	POD 0

The other three covariates (Level of Education, Surgical Pain, and MRSA in the nares) was abstracted from the medical record. Attitude and Behavior was measured with two investigator-developed questions in Likert-Scale format. Demographic variables of age, gender, type of lower extremity surgery was abstracted from the VA's electronic health record (CPRS).

Patient Hand Hygiene Education (Intervention). There are two arms to the Patient Hand Hygiene Education intervention: An electronic audio reminder (EAR), educational video, and handout (Group 1) and an educational video and handout (Group 2). Group 2 did not receive the electronic audio reminder (EAR), but did receive the educational handout and video.

Electronic Audio Reminder (EAR). The concept of an electronic audio reminder (EAR) is novel in its use for patient hand hygiene, but a reminder is something that is applicable to everyday life. It is common for use inside and outside of the healthcare setting from alarm clocks to IV pump alarms. For the purposes of this study, both groups received the educational intervention (handout and video), but only one group received an EAR intervention set with the audio reminder. The EAR was operationalized using a small electronic personal medication alarm clock reminder "Your Minder" system. The system has up to six settings allowing for a voice recording up to six times. For the purposes of this study the alarm sounded times at three time intervals. The voice recording says "Please clean your hands using the hand sanitizer provided." The education only (comparison group) and education plus reminder (intervention group) was operationalized as a categorical independent variable (1=yes EAR and 0=No EAR).

Patient's Four Moments for Hand Hygiene Handout and Video. Two

components operationalize the patient hand hygiene education provided. The first is a one page handout, the “Four Moments of Patient Hand Hygiene”, which specifies hand hygiene practice events similar to the Five Moments of Hand Hygiene (WHO, 2015), an internationally adopted performance guideline for health care staff. The “Four Moments” stipulates times that are crucial for patient hand hygiene: 1) mealtimes 2) exiting and re-entering the patient room 3) contact made with catheters, devices, or wounds, and 4) after use of the bathroom or elimination. As a part of the nursing standard of care, all participants received a copy of this handout to keep on their bedside stand (Appendix A) (Sunkesula et al., 2015) as part of their educational video intervention. A systematic review that examined the effectiveness of videos in modifying health behaviors found that of 28 studies with 12,703 subjects, video modeling for facilitating the learning of new behaviors is effective (Tuong, Larsen, & Armstrong, 2014). Although behaviors such as hand hygiene was not considered for the studies reviewed, the results demonstrate an increase of self-care in patients. Although videos have a long history of educational use, the concept of patient hand hygiene video is novel in its use in this study.

As early as 1981, formal education has been deemed as an important tool in patient care (Bell & Whiting, 1981; McGuckin & Govednik, 2013). Patient education can be tailored to account for different learning styles as the patient-centered approach to patient education provides more value to the patient themselves in adhering to behaviors (Pelzang, 2010). The patient hand hygiene video used for this study was developed with these principles in mind as it targets a specific population, hospitalized veterans and it features veterans educating veteran patients about the “Four Moments” of patient hand

hygiene. The video, which is approximately 1 minute and 29 seconds long, was shown to all subjects on an Apple iPad. The video using animation sketch software with a voice over explains hand hygiene to veterans, by demonstration through active sketch information about healthcare-associated infections, germs, and hand hygiene as a way to clean their hands. It also included the important times when patients should clean their hands in reference to the “Four Moments.” After delivery of the 10-minute intervention (approximate time) by the PI and or trained research assistants, subjects were asked to demonstrate their ability to practice hand hygiene using a teach-back method which is a normal standard of care used within nursing education to patients.

Patient Hand Hygiene Behavior. Patient hand hygiene is defined as the process or act of a patient cleansing their hands with water or liquids that contain water and can include or exclude substances such as soap, antiseptics, alcohol-based hand rubs, and disinfecting wipes (Kampf & Kramer, 2004). In this study, it was operationalized by measuring product consumption of Alcohol-Based Hand Rub (ABHR) and bacterial hand counts. Alcohol-based hand rubs come in a different number of formats such as rinses, foams, and gels. Alcohol is known to dry out if exposed to air which is a part of the processing in being on a patient’s hands (Macinga et al., 2014).

ABHR Product Consumption. Data for product consumption was measured by weighing an 8-ounce container of Purell© Alcohol-based hand rub. Weight measurements were taken at the time of enrollment (baseline). The measurement was taken in grams. In part to avoid the Hawthorne effect or response bias, this study used product consumption rather than observation method or self-report of previous studies. Product consumption measurement was adopted from CDC and WHO

recommendations for measuring healthcare worker product consumption and tailored to accommodate the acute care setting. All measurements were conducted at the same time of day for all participants using identical methods of weighing and recording.

Bacterial Hand Count. Secondly, Bacterial hand counts examined gram-negative bacteria and MRSA, two common aerobic pathogenic organisms found on the hands (Chen, Schreiber, Washington, Rao, & Evans, 2013; Peleg & Hooper, 2010). Gram-negative bacteria cause wound or surgical infections, bloodstream infections such as Klebsiella, Acinetobacter, Pseudomonas aeruginosa, and Escherichia coli and are commonly found in healthcare settings (“Diseases and Organisms in Healthcare Settings | HAI | CDC,” n.d.). The accurate and reliable determination of populated bacteria residing on hands has been found an effective strategy in evaluating the effectiveness of hand hygiene products and hand hygiene methods (Block, 1991; Paulson, 1993). The two hand sampling methods most commonly used to measure the amount of bacterial residual on the hands are the "swab" and the "finger press" techniques (Burton et al., 2011b; “Preparing Spread Plates Protocols,” n.d., “The Streak Plate Protocol,” n.d.). This study used the swab technique. This method avoided the deep pressing that can occur with participants providing the samples directly to the agar plate. If the fingers are pressed too deep on the plate, colony forming units cannot be clearly detected within the agar only on the surface. Bacterial hand counts were measured by colony forming units (CFU) per millileter. A CFU is universally known as the estimated number of viable bacteria in a sample. Gram-negative and MRSA organisms were measured separately, but were measured the same way, as a continuous variable using a paired-t test allowing for the

comparison of two populations: reminder (intervention group) and education only (comparison group).

Covariates. The five covariates of this study as described below are: upper extremity functionality (QuickDASH & Hand Grip Strength), surgical pain, MRSA of the nares, and level of education.

Upper Extremity Functionality.

Upper extremity functionality is comprised of two arms: QuickDASH and the use of a hand dynamometer. Older adults experience loss of strength and manual dexterity with aging, (Manini, Hong, & Clark, 2013; Martin, Ramsay, Hughes, Peters, & Edwards, 2015) which is associated with difficulty performing activities of daily living such as hand hygiene. A hand dynamometer is often used for patients that have hand disabilities or loss of functionality. This requires patients to squeeze a metal device, that provides a manual dial reading in kilograms. The *QuickDASH* an 11-item outcome measure has reliability (Cronbach's $\alpha=.74$) and validity ($r=.75$) in the surgery population (Gummeson, Ward, & Atroshi, 2006a). Using a hand dynamometer as an indicator of Hand Grip Strength is valid and reliable ($ICC > 0.78$, $r > 0.72$)(Mijnarends et al., 2013). The QuickDASH tool uses a 5-point Likert scale that addresses the patients' severity level and function level by answering the appropriate corresponding number. The QuickDASH Scoring Formula = $[(\text{sum of } n \text{ responses})/n] - 1)(25)$ where n represents the number of completed items (Matheson, Melhorn, Mayer, Theodore, & Gatchel, 2006). The QuickDASH cannot be computed if more than 1 item is unanswered on the questionnaire. A higher score indicates a greater level of disability and severity, whereas, lower scores indicate a lower level of disability (Beaton, Wright, Katz, & Upper

Extremity Collaborative Group, 2005; Gummesson, Ward, & Atroshi, 2006b; Matheson et al., 2006). QuickDASH scoring totals range from 0 (no disability) to 100 (most severe disability) (Beaton et al., 2005).

Surgical Pain. Pain, mobility and other limitations such as confinement contribute to a patient's inability to participate in hand hygiene (Landers, Abusalem, Coty, & Bingham, 2012). According to the International Association for the Study of Pain (IASP), the concept of pain is described as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" ("IASP Taxonomy - IASP," n.d.). Pain is an individualized experience. For the purposes of this study pain is a covariate because it is an important symptom experienced following invasive surgery that could affect patient self-efficacy of personal care such as hand hygiene. Pain scores was abstracted from the patients' medical record (CPRS). The measurement of pain using a numerical rating scale has been well validated despite it being self-report. Participants in the study will report their pain to nurses using a scale of 0-10, 0 indicating no pain and 10 being the worst pain experienced. The standard protocols put in place on the surgical unit requires that nursing staff record the patient's pain on admission with the collection of vital signs, post-operative every four hour vital signs, and shift assessments (once every eight hours). The pain score used for this study was the calculated average of Dayshift, Evening Shift, and Night Shift Pains Scores taken for each day (Day 0,1,2,3) for a total of four pain scores recorded. At the Cleveland VA, the pain score is based on scale assessment in the CPRS system captures activities related to pain intensity, duration, location.

Level of Education. The concept of level of education is the highest level of education achieved. Level of education in relation to the study of hand hygiene as a correlation and predictor has been studied among nurses and healthcare workers (Duggan, Hensley, Khuder, Papadimos, & Jacobs, 2008; Dunn-Navarra et al., 2011). Duggan and colleagues found that a higher level of education was associated with a lower level of hand hygiene by healthcare workers (2008). Contrarily, in relation to patient hand hygiene the highest qualified nurses were statistically more likely to have a positive attitude towards patient hand hygiene than lower trained nurses ($\chi^2=29.544$, $P<.001$). (Emma Burnett, 2009). Level of education measurement was extracted from the participants' record (CPRS) from within the Nursing Admission assessment. Every patient admitted to the surgical unit must undergo this assessment. CPRS does not allow the capability of the assessor to leave this area blank otherwise it will not allow for the assessment to be completed. Should the information not be attained from this area, it is also found on the patient profile sheet of the medical record. The information was analyzed in a categorical manner of level of education attended: 1=grade school, 2=middle school, 3=high school, 4=college.

MRSA in the Nares. At the Louis Stokes Cleveland VA, patients are screen as positive or negative for MRSA. For the purposes of this study, Positive=1 and Negative=2. Previous studies show that patients that are carriers of pathogens have a greater chance of carrying colony forming units (CFUs) their hands (Istenes et al., 2013; Kundrapu et al., 2014; Sunkesula, Kundrapu, et al., 2015). For example, a study examining the effectiveness of hand hygiene products, looked specifically at patients with *Clostridium difficile*, patients were shown to have spores on their hands before the

intervention. A study examining the effectiveness of ABHR among patients (N=82) identified as MRSA carriers at the time of admission results indicated that a single application of alcohol significantly reduced the percentage of positive cultures by 82%, $\chi^2(2, 82) = 5, p < .0001$, with 67 patients showing a significant reduction in MRSA CFUs. While the alcohol gel reduced the amount of MRSA on hands, patients that carried a high level of MRSA prior to the use of alcohol gel still had traces left on their hands (Sunkesula, Kundrapu, Macinga, & Donskey, 2015).

Additional Characteristics & Demographic Data Collected

Type of Lower Extremity. Type of lower extremity surgery is the subject's operative site. Subjects receiving non-emergent surgery of the lower extremity involving the joints, muscles, and bones of the hip, knee, foot, and toe was classified into the categories of hip, knee, foot, and toe. This was operationalized using categorical variables: 1= Toe, 2=Foot, 3=Knee, 4=Hip. Type of LE was analyzed as a covariate (predictor variable) using linear multiple regression analysis through the establishment of coded dummy variables. A dummy variable is needed considering this variable is categorical and is less likely to change throughout the study. Dummy variables are "proxy" numeric stand-ins for qualitative facts in a regression model (Pallant, 2013). No relationships between the types of surgery to the lower extremities has been studied or correlated with patient hand hygiene, however it is documented for procedural purposes.

Attitudes and Behaviors. Attitude and behaviors of patients was captured by the following questions: 1) At home, how much do you value clean hands, do you think it is (Likert Scale- Not Important=0 to Very Important=4) 2) At home, how often do you clean your hands at home daily? By clean, I mean wash your hands or use hand sanitizer?

0=rarely (0-1 time) to 3=often (>5 times). Multiple studies have examined that although patients report personal hand hygiene to be important, they don't practice (Emma Burnett, 2009; Istenes et al., 2013; Sunkesula et al., 2015). Patients reported that they do not practice hand hygiene as often as they would at home (Barker et al., 2014). Understanding patient's attitude and behaviors towards hand hygiene can be an indicator or practice or have no relationship with practice.

Preliminary Study

As part of a continuing emphasis on Infection Prevention at the Louis Stokes Cleveland Veteran Affairs Medical Center, a study was conducted on a surgical care unit from August 22, 2014 to September 25, 2014. A collaborative team effort, which included the PI of this dissertation, two of her committee members, an Infection Preventionist, food service workers, and nursing staff, this study examined different facets of patient hand hygiene. Using a multi-stage approach, findings indicated that patients have a high level of knowledge regarding the importance of their own hand hygiene although observation data showed that patients rarely practiced in the hospital. Hand sanitizer was provided to all patients at the time of admission (Sunkesula et al., 2015). Further, a patient hand hygiene intervention facilitated by food service workers, in conjunction with a single-page "Patient's Four Moments for Hand Hygiene" educational handout, was effective; however, use of the handout alone was not (Sunkesula et al., 2015). Building on these findings, it was decided that a next step would be to investigate patient hand hygiene interventions that require less input by healthcare staff. An additional study occurring before this study explored products that the participants would use. After further exploration, it was found that patients find it more convenient and

feasible to use a push down pump with a nozzle. Consequently, this study investigated a two-group intervention. Group 1 received a teaching video, the “Patient’s Four Moments for Hand Hygiene” handout, plus a bedside electronic audio reminder (EAR). Group 2 received the identical teaching video and the “Patient’s Four Moments for Hand Hygiene” handout minus the electronic audio reminder (EAR).

Setting and Sample

Setting. The study site, Ward 5A, is a 36-bed surgery unit in the academically affiliated Cleveland Veterans Affairs Medical Center (Cleveland VA) a public tertiary care medical center focused on patient care, research, and education that serves approximately 105,000 veterans in Northeastern Ohio and surrounding areas. The LSCVAMC acute care areas include four medical-surgical units (Ward 4A, 4B, 5A, 5B), each with 36 beds, with some having a subspecialty.; patients who receive hip or knee surgeries account for approximately 22% of the surgical case load per week (Personal Communication, MA Bobulsky, Quality Management, Cleveland Veteran Affairs Medical Center, April 15, 2015). Average length of stay on Ward 5A is 3-5 days. All patient rooms on Ward 5A has a sink with a soap and paper towel dispenser, a personal bathroom (including an additional sink in the room), and a hand sanitizer dispenser at the door entrance, for healthcare staff and patients to use.

Sample. The study used a sample of post-operative patients, aged 55 years and older, who are admitted to Ward 5A after non-emergent hip, knee, or foot surgery. There are no exclusions based on gender or race but based on the current demographics of veterans admitted to the Cleveland VA for this type of surgery, we expect the sample to

be almost 100% male and approximately 50% African American, the predominant minority population of veterans in Northeast Ohio.

Inclusion criteria. Subjects was included if they:

- Are able to communicate verbally in English.
- < 12 hours following surgery
- Expected to be hospitalized for ≥ 48 -72 hours
- Orthopedic or podiatry surgery

Exclusion criteria. Subjects was excluded if they:

- Have a diagnosis of a dementia related disorder and test positive for cognitive impairment
- Have vision, hearing, or physical impairments that limit interaction with the electronic reminder or require more than minimal assistance to use the study's hand hygiene product.
- Clinical staff recommendation of exclusion due to psychological, social, or physical incapability.

Sample size justification & calculation. This is the first known use of an electronic reminder as an adjunct to patient education for post-operative patients. Cohen (1992) suggests that when effect size cannot be determined from prior research, a sample size for new research should be calculated using a medium effect size, which for regression is 0.15. Calculating the effect size is a necessary measure for determining the sample size needed to demonstrate that the intervention is effective in comparison with the comparison group. Using G-Power 3.0 multiple regression with 6 predictors (Electronic Audio Reminder, Upper Extremity Functionality, Surgical Pain, MRSA in

Nares, Level of Education, Attitudes and Behavior) including the independent variable, an alpha of .05, power of .80, and effect size of $R^2=.15$ requires a total sample size of 56 participants (28 randomly assigned to each group). The sample size was increased to 76 (38 in each group) to address potential attrition due to missing data or participants who withdraw or unforeseen issues such as early discharge, transfer from the unit, or withdrawal of consent. As a result of increasing the sample size the effect size could indicate a greater impact (.11). In examining if there is a difference between the level of bacteria found on the hands of the intervention and comparison groups, a paired t-test was used to perform the analysis. To determine sample size for the research question regarding colony forming units of bacteria on patients' hands, we analyzed an unpublished data set of Curtis Donskey, MD, who specializes in infection prevention and control. In his 2-group sample of 38 (19/group), MRSA was found on the hands of 5% of patients who received hand hygiene education versus on 25% of patient hands in the usual care group. Based on these findings and using an alpha of .05, power of .80, and medium effect size, hand cultures for MRSA and Gram [-] bacteria was collected from a subset of 26 (13/group) of randomly selected participants.

Protocol for Conducting Research

Using a 2-group experimental design and random assignment, Group 1 (n=38) received an educational video, 'Four Moments' handout, and electronic audio reminder (EAR). The EAR advised "Please Clean Your Hands". Group 2 (n=38) received the same identical video and 'Four Moments' handout. A EAR was placed at the bedside of Group 2 participants to ensure the fidelity of the study, however it had the time appear on the display screen, but did NOT sound "Please Clean Your Hands" as the Group 1 device

did. All participants received identical ABHR sanitizing, an 8-oz prefilled push down bottle of Purell Gel (PURELL® Advanced Instant Hand Sanitizer, 3659-12, GOJO Industries, Akron OH). The study site, Ward 5A, is a 36-bed surgery unit in the academically affiliated Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC); patients who receive hip or knee surgeries account for approximately 22% of the surgical case load per week (Personal Communication, MA Bobulsky, Quality Management, Cleveland VA, April 15, 2015). The average length of stay on Ward 5A is 3-5 days. All patient rooms on Ward 5A have a room sink with a soap and paper towel dispenser, a private 3-piece bathroom, and a hand sanitizer dispenser at the door entrance. Enrollment and the intervention began within 8 hours of participants' admission to 5A (after discharge post-anesthesia recovery). Data collection times were the day of surgery (Baseline: POD 0), POD 1, POD 2 and POD 3.

Pilot Study

After IRB approval, the PI tested the protocol for feasibility. Two participants were initially enrolled and completed the protocol. Issues with feasibility and/or the reliability and validity of the instruments such as conflicting nursing unit protocols or guidelines for culturing methods specific to the Louis Stokes Cleveland VA Medical Center was resolved before proceeding. A minor issue was the showing of the video right away. The PI had to use her mobile hotspot because the VA firewall would not approve the video source over the Wi-Fi network. This did not stop the PI from showing the video, but the visit took 5-10 minutes longer.

Human Subjects Protection

This study was approved by the PI's dissertation committee and approved by the

LSCVAMC Institutional Review Board (IRB) and Case Western Reserve University Institutional Review Board (IRB). Recruitment and enrollment included written informed consent detailing the risks, benefits, procedures, and timeframe. Participants were told the study was voluntary and that they had the right to refuse participation or drop out of the study at any time. This was a minimal risk study. Although rare with such short use, participants were removed from the study if alcohol-based hand rub results in skin irritation and peeling and receive appropriate treatment to the affected area. Standard Precautions were maintained for equipment cleaning to prevent cross contamination between participants. There was also the potential risk for the loss of confidentiality. Every effort was made to keep information confidential; however, participants were told that it could not 100% guaranteed.

Study Procedures

The PI attended two regularly-scheduled staff meetings (all shifts) to inform the nursing staff of the research taking place on the unit. A short presentation providing a brief explanation and rationale for the area of research was given. Nursing staff were made aware of the planned duration for the study to occur on the unit (approximately 2-4 months of data collection), the inclusion/exclusion criteria used for recruitment and the procedure for recruiting participants. It was emphasized that the study would not interfere nor add on any additional responsibilities to nursing staff. Nursing staff were provided contact information for the PI and research team members just in case the participants were in need of more supplies or if they have any questions. Following the final analysis of the study, nursing staff received study results and were thanked for their cooperation.

Recruitment and Enrollment

Procedures for Recruiting Subjects. Participants were screened using the electronic health record. As Principal Investigator (PI), I went into CPRS and pulled the surgery and admissions schedules for potential candidates. The PI then went into CPRS to make sure that the potential participant met inclusion/exclusion criteria. If the participants did meet the criteria, the post-operative period was monitored for when the patient would return from the post-anesthesia care unit to Ward 5A.

Based, on the PIs clinical experience, following orthopedic and or podiatry surgeries patient are often resting and eating a light meal. They normally have a pain block. During that time, subjects were approached for the study and provided with the opportunity to enroll.

Informed Consent. Informed consent (Appendix B) was obtained from study participants prior to the initiation of data collection. Informed consent included the risks, benefits, procedures, and the timeframe of the study. This was a minimal risk study. The alcohol-based hand rub sometimes has a harsh effect on the skin that could have resulted in peeling. Participants were asked to contact me if this occurred. There were no physical risks associated with the educational video, handout, or reminder. There was, however, the potential risk of loss of confidentiality. Every effort was made to keep information confidential. Although this process cannot be 100% guaranteed, to date the information is secure. Participants were also made aware that there was no personal benefit to them by participating in the research study. However, they were made aware that it is a known fact that hand hygiene decreases the risk of infection and the potential importance of patient hand hygiene during their hospital stay. They were also made

aware that the knowledge to be gained from this research could have benefited other patients, society, or science as we strive to improve healthcare. As an incentive participant were allowed to take the bottle of hand sanitizer home and received \$10 in cash on the last day of data collection. Participants were also told that the study was voluntary and that they had the right to refuse any part or drop out of the study at any time. Reassurance of confidentiality regarding participant's specific information was discussed. Participant information includes material from participant recruitment, enrollment, during, and after data collection. If the participant did agree to enroll, their first initial and last initial and year of birth was recorded as the Participant ID at the top of the participant form (Appendix C).

The numbers of patients who refused and number of drop-outs were also recorded. Subjects were asked to participate and sign the informed consent. Analysis of rejected and enrolled subjects can provide information in need of discussion or information needed for post-hoc analysis. Collection of this information helps to minimize selection bias which could affect the results between the two groups in this study. For example, the enrollment of more orthopedic participants versus podiatry participants could have an effect on analyzing the results if a balance doesn't exist. This is why randomization is important. Attrition bias could also occur, causing differences between certain types of participants withdrawing from the study. A Type I or Type II-Error can occur depending on the magnitude of bias on the study. Therefore, it is important to be aware of bias.

Randomization and attrition. Following enrollment, subjects were assigned to one of two groups using a minimization randomization computer program. Assumptions

include a reasonable conservative attrition rate of 20%. The devices were numbered and any device that was decided by a “2” was indicative of Group 1 (intervention group) and received a sticker. All rooms received the electronic audio reminder even though only those marked with a sticker provided the patient a reminder. The same process was used to randomize participants that will receive hand swabs with an additional sticker being placed on the ABHR. Participants enrolled in the study were randomized again to determine if they were receiving hand swabs. Only a subset (34 participants) from both the EAR group and the comparison group (without the EAR) had their hands swabbed.

Following Informed Consent to Intervention

All participants were provided with a ‘Patient’s Four Moments for Hand Hygiene’ handout. All participants received receive the Four Moments hand-out, a picture graphic text indicating to patients four important times to clean their hands. Both groups received an 8-oz push down bottle of Purell Gel (PURELL® Advanced Instant Hand Sanitizer, 3659-12, GOJO Industries, Akron OH) noted as alcohol-based hand rub (ABHR) to clean their hands. It was placed on the participants’ bedside table and they were asked to do a return demonstration of ABHR use. Each bottle was marked “For Patient Use Only” to increase the chances that only participants would use it. This information was also explained clearly in the consent for that family members should use other resources in the room. The ABHR was measured for an initial weight with the adhesive Velcro-attached to the bottom so that it could be placed at the bedside table.

Participants in both groups were shown a hand hygiene educational video. The video was viewed by all study participants with closed captioning on an iPad at baseline and was watched up to two times. All of the participants saw the video; however, none of

them saw the video more than once. Participants in both groups received education about the electronic audio reminders (EAR). The EAR is a digital clock; all participants were told that it can help them remember to clean their hands. The EAR is a voice-recorded hand hygiene reminder prompt. A voice recording was chosen to increase acceptability and lessen the chance for it to be confused with medical device alarms. The EAR reminded participants in Group 1 to clean their hands three times per day: 12pm (before lunch), 5pm (before dinner), and 7pm). Seventeen of the 41 patients in the intervention group had family members record their message asking them to clean their hands at the time intervals indicated. Participants receiving the intervention were asked to do a return demonstration that they could turn off the red colored “acknowledge alarm” button. This is a necessary step to stop the reminder from constantly repeating itself. Participants that received a non-activated EAR were told that the EAR was an alarm clock that would be placed on their bedside table during the time of the study.

Data Collection

Covariates and Demographics. Both groups were asked to squeeze a hand dynamometer three times; the best of squeezes was recorded in kilograms. The Quick Disability of Arms, Shoulders, and Hands (QuickDASH) assessment a 11-item interview questionnaire was asked verbatim followed by the Attitudes and Behavior Questions about hand hygiene habits at home. These questions were asked at the time of enrollment. Following the initial visit, the PI then recorded demographic information and covariates from CPRS such as MRSA in the nares was on the participants’ data collection form.

Measurement for the alcohol-based hand rub (ABHR) by a digital scale to measure weight (grams) was taken at baseline for all participants and then once a day for

participants thereafter on POD 1 and POD 2. On POD 3, the measurement was taken by 1pm due typical discharge timeframes on Ward 5A. At that time, the EAR was checked for quality improvement in terms of if it was still placed at the bedside and if patient had received any reminders throughout the day. Two hours after the last EAR reminded the intervention group (at 7pm), data for ABHR weights was collected. The digital scale was placed consistently on the same hard surface to ensure consistency. The digital coding of the scale went out to the ten-thousandths place for accuracy.

Hand Cultures. The main outcome of the study is to measure if there is an increase in hand hygiene practice as a result of the intervention. However, as a secondary outcome, randomization software was used as previously indicated to perform hand cultures. From each group, 17 participants for a total of 34 had their hands cultured at baseline (at enrollment) and on the last day of the study. Two cotton swabs was used to swab the dorsal and ventral part of hands and in between the finger nails. This information was coded using the same Participant ID used for the other data collection for the patient. Lab information was de-identified and taken to Dr. Donskey's lab for processing within 24-48 hours of swab collection.

The following steps were taken to swab the samples onto plates:

1. Using the sample swab, the swab was streak back and forth on one half of the plate (quadrant A) as shown below in Figure 2
2. The swab was then turned over to streak on the plate (in the same back and forth pattern) but in the opposite direction from step 1
3. Steps 1-2 were repeated on the other half of the plate (quadrant B) as shown below in Figure 2

4. Plates were placed media side up in the incubator for 24-48 hours for growth
5. Colony forming units (clusters of bacteria was sought) to count by quantity.

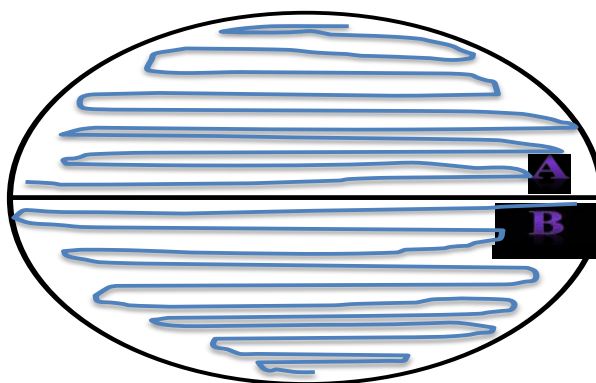


Figure 2 Swabbing Technique Used for Hand Cultures

Standard of Care Procedures

Pain scores and vital signs were collected from orthopedic and podiatry patients as seen fit. If patients required assistance with care, PI assisted nursing staff to provide care within the PIs scope of practice as a registered nurse. PI was sure to use standard precaution including hand hygiene between each and every patient. Minimal materials were taken in the room to minimize the risk of cross contamination. For example, materials only for the participant being enrolled were taken in the room. Devices were cleaned using a EMS Approved surface cleaner in between patient use.

Fidelity of the Study

A procedural manual for the protocol was created. A scientifically calibrated scale measured all participants' product consumption. The reliability of the scale was measured for interrater reliability by a second researcher that checked to ensure the weight of

random items matched, there was no difference bigger than .01 grams. Product consumption was checked every 24 hours. To minimize staff bias, the EAR was placed on the bedside stands of both Group 1 and Group 2 participants. The EAR is a digital clock; all participants was told that it can help them remember to clean their hands. Randomly, in an unobtrusive manner the PI checked the EAR at one of the three time intervals to ensure that the alarm went off. Only the PI knew which devices had the audio reminder set at the time intervals which was indicated by a sticker on the device. The PI visited patients in both groups for an equal amount of time each day to minimize attention bias.

Data Safety

Participants' data were protected in several ways. Identifiable participant information (consents and a list linking patient name and study ID) were stored in a locked drawer in the PI's Office. The laboratory area is secure requiring special authorization to enter, however agar plates were identified only by study ID. All electronic data was stored in a password-protected computer during the study and was afterwards. Data collection instruments were inspected for completeness immediately upon completion. Data were entered into SPSS (Statistical Package for the Social Sciences). Data were examined for outliers and out of range values addressed. A Manual of Operations detailing all data collection forms and procedures related to the protocol ensured proper data collection and management Data safety was monitored: 1) consent forms being separated from the instruments, 2) the PI and PhD Advisor Dr. Higgins met weekly to review procedures and data management 3) possible threats to data safety were

discussed. Access to the database was limited to the PI, her PhD advisor, and the IRB committee.

Completion of Data Collection. In order to minimize missing data, data collection instruments were inspected for completeness and clarity immediately upon completion. Upon completion of each participant from the study the electronic reminder was removed from the rooms. The final collection of containers weighed and final hand cultures were collected. Once a complete set of data per participant was received the participant received \$10 for their participation. Participants were asked to sign a receipt book indicating that they received their incentive of \$10. All collected data were stored as previously discussed. Electronic participant information was stored on a password protected computer in a locked office and written participant information was stored under lock and key in a file cabinet in the PIs office at the LSCVAMC. A summary of the intervention protocol is listed below in Table 2.

Table 2 Timeline of Intervention Implementation

Model	Variables and Measures	Measurement			
		Post-operative Day (POD) 0	Post-operative Day (POD) 1	Post-operative Day (POD) 2	Post-operative Day (POD) 3
Outcome:	▪ Alcohol-based hand rub consumption (ABHR) (grams)	x	x	x	x
	▪ Colony Forming Units (CFU)	x		x	x
Independent Variable	▪ Educational Video & Handout (Comparison Group 1)	x			
	▪ Educational Video, Handout, and Electronic Audio Reminder (EAR) (Group 2)	x			
Process variables:	▪ Total # of Electronic Audio Reminder (EAR)	x	x	x	x
	▪ Education	x			
Covariates:	▪ Upper extremity functionality	x	x	x	x
	▪ Surgical Pain	x			
	▪ MRSA in nares	x			
	▪ Attitude and Behaviors	x			
	▪ Level of Education	x			

Data Management and Safety

Ms. Knighton with the help of her dissertation committee analyzed the data collected. Descriptive statistics was used to describe univariate characteristics of demographic factors including age, gender, type of lower extremity surgery, and the covariates: *QuickDASH*, *hand grip strength*, *surgical pain*, *MRSA in the Nares*, *attitudes and behavior*. This study's parametric tests included multiple regression and paired t-test. Hypothesis 1 was analyzed using multiple regression analyses. Hypothesis 2 was analyzed using multiple regression analyses. Using a paired samples t-test, the change in CFUs (MRSA and Gram-Negative organisms) from POD 0 to 3 was used to determine if the intervention (EAR) made a difference in the level of bacteria detected on participants' hands. Data were examined for statistical assumption violations. If the assumptions were not met, the data were examined to see if the violations were detrimental to the analysis. If a robust violation occurred, the transforming and or removal of variables were necessary in addition to the retesting of the data. According to Fields (2013) if the results were similar after the modifications were made, to maintain the integrity of the data, all of the original data were restored. A number of methods were considered to address missing data, but for best rigor, missing data should be treated using Expectation Maximization (EM) instead of deletion (2002).

Data Management and Cleaning

Data were entered into SPSS (Statistical Package for the Social Sciences). To minimize entry errors, data were entered twice. After all of the data are entered, outliers or out of range values for each variable was inspected using distributions. The data input on participant data collection sheet was compared and checked for inaccuracies by a

second researcher. To ensure that the information recorded on the participant data collection forms were identical to what was put into SPSS, the second researcher looked participant ID followed by the data recorded. Following validity checks and accounting for errors and discrepancies, information was stored in multiple secured places to ensure it was not lost such. These storage places include as the PI's locked and secured file cabinet in the PI's locked and secured office, the secured laboratory facility in which the culture analysis was performed, and on the password-protected computer of the PI.

Data Analysis

Descriptive statistics, including central tendency, dispersion, distribution, frequencies, means, and medians were used to describe univariate characteristics and demographic factors including age and gender, type of lower extremity surgery, level of education, mobility, and pain.

Parametric tests included multiple regression and paired t-test. For t-tests analyses, assumptions for paired t-tests, interval level of measurement for the dependent variables, random samples, normal distribution, and homogeneity of variance was examined for violations. For multiple regressions ensuring acceptable variance, no influential cases, linearity, constant error variance, and normally-distributed error variance was examined for assumption violations. If the assumptions are not met, the data were examined closely to see if the violations are detrimental to the analysis. If a robust violation occurred the transforming and or removal of variables was necessary in addition to the retesting of the data. According to Fields (2013) if the results are similar after the modifications are made, to maintain the integrity of the data all of the original data should be restored. A number of methods were considered to address missing data, but according

to Musil and colleagues, for better rigor of the study missing data should be treated using Expectation Maximization (EM) instead of deletion (2002).

Analysis for each of the research questions is discussed below:

***RQ1.** Do participants in Group 1 (EAR) have better rates of Patient Hand Hygiene Behavior (alcohol-based hand rub and colony forming units) than those in Group 2 (No EAR).* Univariate analysis will be used to measure ABHR consumption and multiple regression analyses were used to determine if there are predictive relationship among the independent predictor variable of the patient hand hygiene education and the EAR intervention and the dependent outcome variables of patient hand hygiene behavior as measured by weight and colony forming units.

***RQ2.** Controlling for 5 covariates (QuickDASH & Hand Grip Strength, Surgical Pain, MRSA of the nares, Level of Education) is the Electronic Audio Reminder (EAR) a predictor of product consumption (ABHR use)?* Using a paired samples t-test, the change in amount of alcohol-based hand rub consumption from Day 0 to Day 3 was used to determine if the intervention (EAR) makes a difference in the amount of ABHR product consumption.

Threats of Validity in the Study

Threats of Internal Validity. Internal validity is the concept that consistency exists between the theoretical and statistical relationship among variables in the study (Higgins & Straub, 2006). Internal threats are unexpected occurrences that are identified after data collection is complete. It was important to anticipate possible about potential threats considering the same data can't be captured again once it is collected. Internal

threats could have potentially affected the relationships that may or may not exist between independent and dependent variables. Potential threats to internal validity expected were concurrent events (unrelated events occur during collecting data, and influenced relationships among variables), differential selection of participants and differential loss of participants (bias occurring systematically that could influence recruitment) due to the unknown variation of participant dropouts or being able to get complete samples. The assurance of consistent measurement of outcome variables could have been a major issue that could produce a Type II error. Occurrences such as placement of the bedside table was presumed to be generalizable to the sample. These processes were closely monitored for adherence to protocols.

Post-hoc analyses were done to closely examine data for relationships to internal threats. Mortality was one of the biggest threats which could have affected the differences between Group 1 and Group 2 drop-out rate of subjects causing them to be unequal. No patients dropped out of the study. Internal threats to be conscious of are specific events (history) that could occur between different times of data collection. For example, the processes for admission or the use of certain drugs or hardware for surgical patients change during the time of the study altering participants' health. This did not occur during the study, but provides an example that this was considered. Swabbing the hands "testing" of both the intervention and comparison groups could have had an impact on product consumption thus increasing their behavior in anticipation of getting their hands swabbed. The EAR did not malfunction to our knowledge and were checked every 24 hours for functional issues. To account for all of these, it was important to make sure that protocols were put in place, tested for clarity, and carried out.

Threats of External Validity. External validity examines how generalizable a study can be made in relation to population, place, and time (Higgins & Straub, 2006). The use of this specialized was a threat to external validity. This study is being conducted among the older adult, veteran, predominantly male, post-operative orthopedic population. The small sub-sample of women enrolled in study the exclusion of younger age groups, in addition to other types of medical conditions requiring hospitalization presents sampling bias, an external threat to validity.

Findings from this study were not generalizable. The use of statistical conclusion validity in relation to random and systematic error was used to explain the difference between statistical and clinical significance. Errors of instrumentation (reliability issues) can pose a risk to statistical conclusion validity, thus making the methods and protocol used for this study essential to the rigor of this study.

Summary

The protocol for conducting the research study described in this chapter was essential to its success. Proper collection and analysis of data ABHR product consumption, hand cultures, and demographic data helped to provide insight to the effectiveness of education strategies among the intervention and comparison groups. The analyses of these statistics provide the foundation for understanding how to implement patient hand hygiene practices in healthcare settings. The statistical results including the assumptions will be addressed in Chapter 4.

Chapter IV

Results

The purpose of this study was two-fold: to determine if education (an active cued reminder) and the provision of readily accessible resources could improve patient hand hygiene and two, to determine if patients could achieve autonomy of routine patient hand hygiene practice with little or no staff input. This 2-group comparison study tested the effectiveness of two educational-based approaches to improve patient hand hygiene in older veterans hospitalized for elective lower extremity orthopedic or podiatry surgery. Convenience sampling and random assignment was used to create the two groups: Group 1 received an educational video, an educational ‘Four Moments’ handout, and an electronic audio reminder (EAR), that prompted the participant to clean their hands three times during wake hours with alcohol based hand rub (ABHR). Group 2 received the educational video and ‘Four Moments’ handout. Participants in both groups were provided with identical pump bottles of alcohol-based hand rub. The Patient Hand Hygiene Model (Figure 1) was used to guide this study. All data were screened to identify any missing data, miscoding, and outliers.

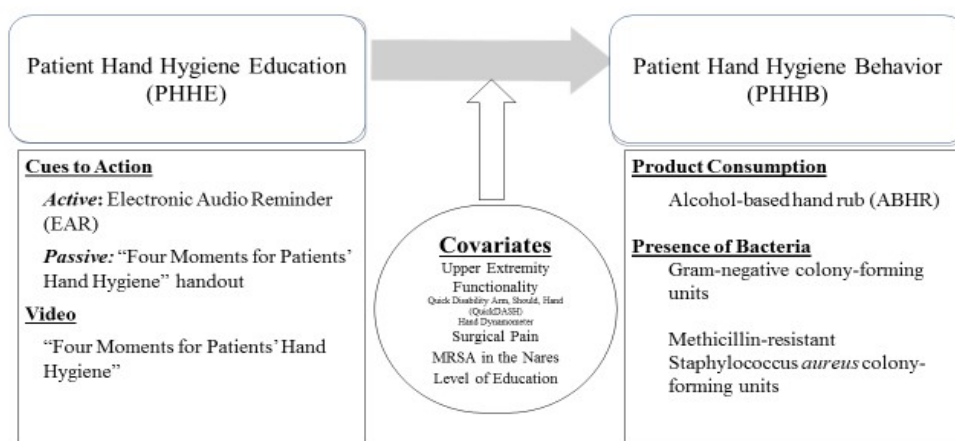


Figure 1 Repeat from Chapter 1 of Patient Hand Hygiene Model

All analyses were performed on normally distributed data after the assumptions for parametric testing were evaluated. Assumptions of normal distribution, adequate variance of variables, and linearity were met for all statistical analyses.

A description of study sample demographics is provided in this chapter followed by the results for each research question. A comparative effectiveness design, multiple methods of data collection, and multivariate analyses were used to answer the following research questions:

- 1) *Do participants in Group 1 (EAR) have better rates of Patient Hand Hygiene Behavior (alcohol-based hand rub and colony forming units) than those in Group 2 (No EAR).*
- 2) *Controlling for 5 covariates (QuickDASH & Hand Grip Strength, Surgical Pain, MRSA of the nares, Level of Education) is the Electronic Audio Reminder (EAR) a predictor of product consumption (ABHR use)?*

Description of Sample

Setting and Sample

Following approval by the hospital and the university's Institutional Review Boards (IRB), eligible veterans were recruited and enrolled in the study. Potential participants were recruited from a surgical care ward, a 36-bed unit in a public tertiary care medical center focused on patient care, research, and education that serves approximately 105,000 veterans in Northeastern Ohio and surrounding areas. The ward specializes in pre-operative and postoperative care of veterans receiving orthopedic, podiatry, general surgery, cardiothoracic, urology, and or vascular surgeries. Average length of stay on the ward is 3-5 days. All patient rooms on the ward have a sink with a

soap and paper towel dispenser, a personal 3-piece bathroom, and a hand sanitizer dispenser at the door entrance, for healthcare staff and patients to use.

Recruitment & Enrollment of Sample

Throughout the timeframe for data collection (August 2016- November 2016), all LE post-surgical orthopedic patients who were >55 years of age were eligible for the study. Eighty-seven patients met initial inclusion criteria and 84 were approached to participate in the study. Patients who were not approached were unavailable were 1) admitted to the ward beyond the 12-hour eligibility time period; 2) had a planned early discharge and 3) were unavailable due to hospital procedures. Of the 87 eligible, 3 (3.4%) were unavailable and 9 (11%) patients declined, leaving a sample size of 75 enrolled participants. Participants that declined volunteered to share their reason for not wanting to be in the study. Some participants stated “too much going on for me right now.” A second common reason was the preference for soap and water over alcohol-based hand rub. Those patients who declined to be in the study had a slightly lower mean age (65.1 years) than the study participants mean age (65.6 years); 6 (66.7%) were white and 3 (33.3%), black. No cases were eliminated from the data analysis, leaving a total of 75 subjects. Figure 3 shows the process of sample selection.

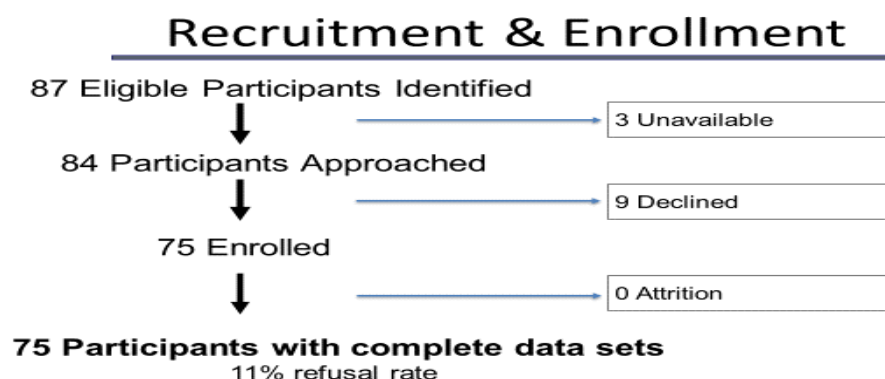


Figure 3 Sample Selection for Research Study

Sample Description. Descriptive characteristics of the study sample are presented in Table 3 and Table 4. The data in Table 3 are from the hospital's computerized patient record system (CPRS). Table 4 data, collected from the participants, is presented by group: the EAR or intervention group (Group 1) and the comparison group (Group 2). Table 5 provides data from the questionnaires about participants' attitudes and behaviors.

Table 3 Participant Characteristics and Demographics N=75

<i>Demographics of the Sample (N=75)</i>	<i>N (%)</i>
Gender	
Males	70 (93.3)
Females	5 (6.7)
Participant Age in Years (Mean/SD)	65.6 (SD)
Range	55-87
Race n(%)	
White	59 (78.7)
Black	15 (20)
Pacific Islander	1 (1.3)
Methicillin-Resistant Staphylococcus Aureus Nares Status on Admission	
Negative	74 (85.9)
Positive	14 (14.1)
Type of Surgery 75 (100%)	
Toe	4 (5.3)
Foot	20 (26.7)
Knee	27 (36.0)
Hip	24 (32.0)
Highest Level of Education 74 (%)	
College	21 (28.0)
High School	42 (56.0)
Middle School	4 (5.3)
Grade School	8 (10.7)

*p <.05 significant

Table 4 Participant Demographics and Characteristics by Group

	Electronic Audio Reminder n=41 (54.7%)	No Electronic Audio Reminder n=34 (45.3%)
Participant Age M (SD)	66.29 (1.33)	65.50 (1.29)
Range	55-87	55-81
Gender n (%)		
<i>Male</i>	40 (97.6)	30 (88.2)
<i>Female</i>	1 (2.4)	4 (11.8)
Ethnicity n (%)		
<i>Caucasian</i>	31 (75.6)	28 (82.4)
<i>Black</i>	9 (22)	6 (17.6)
<i>Pacific Islander</i>	1 (2.4)	
Highest Level of Education Attended n (%)		
<i>Grade School</i>	3 (7.3)	5 (14.7)
<i>Middle School</i>	2 (4.9)	2 (5.9)
<i>High School</i>	24 (58.5)	18 (52.9)
<i>College</i>	12 (29.3)	9 (26.5)
Type of Surgery n (%)		
<i>Toe</i>	2 (4.9)	2 (5.9)
<i>Foot</i>	8 (19.5)	12 (35.3)
<i>Knee</i>	15 (36.6)	12 (35.3)
<i>Hip</i>	16 (39)	8 (23.5)
MRSA in the Nares at Admission n (%)		
<i>Positive</i>	4 (9.8)	6 (17.6)
<i>Negative</i>	37 (90.2)	28 (82.4)
Hand Cultures obtained? n (%)		
<i>Yes</i>	21 (51.2)	11 (32.4)
<i>No</i>	20 (48.8)	23 (67.6)
Hand Dynamometer: Average of 3 scores (kg)		
Mean (Standard Deviation)	56.59* ± 29.7	37.65* ±17.11
Range	10-140	10-80
Surgical Pain Score Average (0-10)		
Mean (Standard Deviation)	4.83 (.267)	4.97 (.355)
	2.82 (1.50)	5.48 (1.94)
Total QuickDASH Score		
Mean (Standard Deviation)		
Range	0-54.55	0-40.91

P<.05* is Significant

Table 5 Attitudes and Behaviors of Participants about Patient Hand Hygiene

	Electronic Audio Reminder n=41 (54.7%)	No Electronic Audio Reminder n=34 (45.3%)
Attitudes and Behavior Question 1		
How much do you value clean hands? n (%)		
Neutral	1 (2.4%)	1 (2.9%)
Moderately	7 (17.1%)	5 (14.7%)
Very Important	33 (80.5%)	28 (82.4%)
Attitudes and Behavior Question 2		
How often do you clean your hands at home and by clean, I mean use hand sanitizer or wash your hands? n (%)		
		5 (14.7%)
Occasional/Sometimes	2 (4.9%)	
Almost Every time	39 (95.1%)	29 (85.3%)

Research Question 1

“Do participants in Group 1 (EAR) have better rates of Patient Hand Hygiene Behavior (alcohol-based hand rub and colony forming units) than those in Group 2 (No EAR).” RQ1 was answered with data obtained from daily weights of the study participants’ new bottle of commercially available Purell© alcohol-based hand rub. Each bottle was approximately 240 grams; each bottle was newly opened at the participant’s bedside and measured every day for 3 days.

Product Consumption

Participant data collection began on POD 0 (the day that participants had surgery and were admitted to the study). Twenty-four hours from the time of surgery was counted at post-operative day 1 and so forth. Alcohol-based hand rub product consumption was measured with a digital scale (Adam Equipment CBK 8a Portable

Bench Scale, 8lb/4kg Capacity, 0.0002lb/0.1g Readability). A univariate Paired T-Test was used to examine the differences in mean product consumption between Day 0 & Day 3 and the results indicated that there were statistically significant differences among the means of ABHR use on Days 1, 2, and 3. Table 6 below shows there were significant group differences in product consumption on all days of the study. The results are shown by group (EAR and No EAR) in Table 6.

Table 6 Alcohol-Based Hand Rub Gel Bottle Weight & Product Consumption (grams)

	Patient Get EAR? (N=75)	N	M	SD	Lowest	Highest	t	p
Bottle Weight Day 0	Yes	41	243.97	3.06	238.9	251.2	.126	.900
	No	34	243.88	3.42	235.9	250.4		
Bottle Weight Day 1	Yes	41	235.40	6.12	215.6	244.3	-3.766	<.001
	No	34	240.27	4.82	227.7	250.4		
Bottle Weight Day 2	Yes	41	225.75	10.99	200.0	243.2	-4.937	<.001
	No	34	236.52	7.03	212.9	248.7		
Bottle Weight Day 3	Yes	41	214.01	17.41	182.3	241.0	-5.696	<.001
	No	34	232.99	9.46	201.0	248.6		
Difference in product consumption between day 0 and 3	Yes	41	29.97	17.13	4.50	60.50	5.822	<.001
	No	34	10.88	9.27	1.80	38.40		

Participants in both the EAR and No EAR groups used the ABHR. On Day 0, the day that participants were enrolled in the study, measurement weights were taken at baseline immediately after the bottle was opened, but before any use occurred. Both groups had similar means for product consumption on Day 0 which is to be expected considering neither group used it before the initial weight. Results show that there was a mean difference in product consumption between groups beginning on Day 1 with

the Ear group using 4.87 grams more the first day and 10.77 grams more use on Day 2 by the EAR Group. Mean product consumption between Day 0 and Day 3 also differed showing that the EAR group used 29.97 grams of ABHR in comparison to the non-EAR group (10.88 grams).

Bacterial Hand Counts

In total, 32 patients' hands were cultured. For Group 1 (EAR) 21 of 41 (51.2%) participant hands were cultured and analyzed per the standard protocol. Group 2 (No EAR) had 32.4% (11 of 34) participants had hand cultures. In analyzing the laboratory data, results indicated that there was no growth of colony forming units for either group. Consequently, no statistical analyses were performed.

Research Question 2

“Controlling for 5 covariates (QuickDASH & Hand Grip Strength, Surgical Pain, MRSA of the nares, Level of Education) is the Electronic Audio Reminder (EAR) a predictor of product consumption (ABHR use)?” RQ2 was answered using standard multiple regression was used to compare consumption on Post-operative Day (POD) 0 to up to POD 3, controlling for the five covariates: Disability of Arm, Shoulder, and Hand (QuickDASH), Hand Grip Strength, Education, Surgical Pain, and MRSA. The major assumptions for multiple regression results were examined and checked as a part of the multiple regression analyses. Simultaneous multiple regression analysis allowed determination of the contribution of the independent variables (Disability of Arm, Shoulder, and Hand (QuickDASH), Hand Grip Strength, Education, Surgical Pain, and MRSA in Nares) to ABHR product consumption. To avoid inflated likelihood of error by using the p-value of .05, we used an adjusted p-value to test for significance.

Regression results in Table 8 shown below for Model 1 indicated that the electronic audio reminder of the covariates was significant predictors of ABHR consumption, $R^2 = .39$, $R^2_{\text{adj.}} = .34$, $F(6, 68) = 7.265$, $p < .001$. $R^2 = .34$ demonstrating that the predictors for 34% variance in ABHR product consumption.

Part correlation coefficients are also referred to as *semi partial correlation coefficients* (Tabachnick and Fidell 2013, p.145). If this value is squared, it provides an indication of the contribution that the variable makes to the total R square. In other words, it will indicate how much of the total variance in the dependent variable is uniquely explained by that variable and how much the R square would drop if the variable was not considered as a part of the model. For this study, the *semi partial correlation coefficients* for hand dynamometer was 0.181, squared shows that *hand dynamometer* accounts for 3.2% of variance explained of the total R square .34. The *electronic audio reminder* part correlation .448 squared accounts for 20% of the total variance explained. *Level of education and MRSA Status*, accounted for less than 1% of total variance explained. The *QuickDASH* scores and *pain* average each accounted for approximately 1% of variance explained. These square part correlation values do not equal the total R square because the part correlation values only represent the unique contribution of each variable, thus any overlap or shared variance is removed. The total R square includes unique and shared variance.

Model 1 includes 6 predictor variables including the use of the electronic audio reminder (EAR), explains 34% of the variance in the outcome, patient hand hygiene practice as measured by product consumption. Of the 6 predictor variables examined, the EAR makes the largest contribution ($\beta = 15.86$), although the hand dynamometer

shows statistical significance as shown in Table 7 below. The beta values obtained in this analysis can also be used for more practical purposes than theoretical model testing (Tabachnick and Fidell 2013) such as understanding if certain parts of the intervention or covariates can be used to advance other areas of research. For example, maybe education was not a factor in this study, but provides enough evidence that it influences behavior. Furthermore, it indicates the unique contribution that each variable has to product consumption. Standardized beta values indicate the number of standard deviations of grams of product consumption would change if the predictor variable was to change by one standard deviation. The beta value with the largest number (ignoring the negative signs in front) demonstrates the strongest contributor to product consumption. In this case within the margin of 1 standard deviation, product consumption would drop by 15.86 grams if the EAR intervention was deleted from the model.

Table 7 Model Coefficients

	Variable	B	B SE	β	t	Sig.
Model						
1	Constant	11.03	6.37		1.732	.088
	Hand Dynamometer ²	.001	.001	.268	2.59	.012
	QuickDASH Total	-.215	.155	-.132	-1.39	.169
	Education Level	-1.35	1.85	-.070	-.733	.466
	MRSA Status at Admission (Yes/No)	-.911	4.66	-.018	-.196	.845
	Average Pain Score ³	.015	.009	.149	1.60	.115
	EAR (Yes/No)	15.86	3.38	.468	4.68	.000*

*P-value significant at .05 level

a. Variable linearity squared

b. Variable linearity cubed

After performing the analyses of the results to ensure accuracy, the assumptions were addressed for this study.

The EAR and hand dynamometer variables meet this standard indicating an inverse relationship (-.314). The predictor variables were also assessed to ensure that none of them were too high or near 1.0. Typically, highly scored variables near a correlation of 1.0 could indicate that there is no difference between the two variables in this study; this did not occur therefore all variables were retained. According to Tabachnick and Fidell, correlations above .3 either positive or negative is preferred. (2013). IBM SPSS also performed 'collinearity diagnostics' on the variables in the model as a part of multiple regression procedures. This addresses any problems that may have not been detected in the correlation matrix. Typically, if there is a violation of this assumption, I would have to remove one or more of the highly intercorrelated independent variables from the model. The results are presented in (Appendix D) as "Coefficients" and two values are given: Tolerance and Variance Inflation Factor (VIF). Tolerance is an indicator of how much of the variability is not explained by other independent variables in the model and is calculated using 1-R squared for each variable. If the values are less than .10 or smaller, it indicates that multicollinearity is possible suggesting that multiple correlation with other variables is high. Appendix D shows that this study met the assumption for multicollinearity. The lowest value for Tolerance was .758 and .986 for the highest. VIF is the inverse of Tolerance. The VIF cutoff is 10. Anything beyond 10 indicates violation of this assumption. In this case, the VIF range was 1.043-1.318 which is sufficiently beneath the threshold of 10 before it is considered a violation. I have not violated the multicollinearity assumption.

Another way that my assumptions were checked was by inspecting the Normal Probability Plot (P-P Plot) of the Regression Standardized Residual and the scatterplot. In the Normal P-P Plot, the points did lie in a reasonably straight line from bottom left to top right indicating that I had no major deviations from normality. In the scatterplot of the standardized residual, the residuals were roughly in a rectangular format which is normal and fell between the values of -1 and 1. None of the residuals in the scatterplot followed a systematic pattern, therefore I did not violate this assumption. There were no outliers in the scatterplot, none of the residual points were more than 3.3 or less than -3.3 (Tabachnick and Fidell 2013). Outliers were also checked by examining the Mahalanobis distances produced by IBM SPSS. For 6 predictor variables, the critical value is 22.46 (Tabachnick and Fidell 2013). Case 40 value of 26.40 statistic does fall slightly outside of the critical value, however it is not uncommon for this to occur therefore this case will not be excluded from data analysis. This decision was based on further examination of the Cooks Distance, which tells us if Case 40 will have any undue influence on the results of our model as a whole. Cases with values higher than 1 are a problem and in this case no cases had a value higher than 1. All of the assumptions including normality, linearity, multicollinearity, and homoscedasticity for Research Question 1 have been met.

Summary

The results from this study show that education increases hand hygiene practice in hospitalized patients who have limited mobility due to lower extremity surgical intervention. Furthermore, results indicate that the electronic audio reminder is an effective adjunct to patient education. This study also provides insight on multi-modal strategies that can be used for future research in improving patients' self-management of

hand hygiene practices. Additionally, the analyses indicate that there is partial support for the study model. Further interpretation and discussion of these relationships will be discussed in Chapter V.

Chapter V

Discussion

This chapter is a discussion of findings, interpretation of the findings, and conclusions. The implications of the findings for nursing and policy recommendations for future studies will be made. The study model will also be evaluated. Furthermore, limitations of this study will be discussed. Suggestions for future research in the areas of patient hand hygiene behavior, the use of electronic-audio reminders (EAR) or electronic devices to facilitate self-management, and implications for hospitalized adult medical patients will also be explored. Finally, a summary will be presented.

In recent years Infection Preventionists have focused their attention on patient hand hygiene. Of note, substantial research has indicated that hand hygiene is one of the most important, easiest, and inexpensive practices in preventing infections. Principles of hand hygiene, guidelines, and standards for healthcare worker hand hygiene have established a foundation for growth and improvement; however, the continued prevalence of healthcare-associated infections highlights the need to expand our efforts including investigating the role of patients in infection prevention. It also is recognized that patients have a different set of challenges than healthcare workers; for example, mobility issues, knowledge deficit about hand hygiene. Patient hand hygiene research is emerging and consequently it is important to make sure that patient-centered solutions are targeted to preventing healthcare-associated infections and are tailored to the needs of patient populations. Instances that warrant improved hand hygiene in the institutional setting stem from the reality that pathogenic organisms are present in human body substances, on surfaces surrounding or attached to the patient such as bedrails and

medical devices. The lack of hand hygiene by patients may contribute to the transfer of these organisms to compromised body sites thus resulting in healthcare-associated infections. The lack of extensive research in the area of patient hand hygiene interventions warranted the need for this study as a way to generate data that could potentially address barriers and improve patient hand hygiene practice.

Older adult patients have ambulatory limitations in the immediate post-operative period as a result of lower extremity surgery which could inhibit their ability to access the sinks and hand sanitation dispensers on the walls. As a medical/surgical staff nurse working on a surgical unit with patients receiving lower extremity surgery, I repeatedly observed the disregard for personal hand hygiene (especially hand hygiene) practices by patients. Recent studies validate my observations in demonstrating that patients have poor hand hygiene practice rates similar to those of healthcare staff (Cheng et al., 2016; Srigley et al., 2014). Very few studies have focused on the hand hygiene practices of surgical patients or older adults and of the studies that focused on the surgical population they did not test an intervention that was intended to increase patient's independent hand hygiene practices. The purpose of this study was two-fold: to determine if education (an active cued reminder) and the provision of readily accessible resources could improve patient hand hygiene and two, to determine if patients could achieve autonomy of routine patient hand hygiene practice with little or no staff input. One such approach, used in this study, was to increase the independent practice of hand hygiene by testing the use of an electronic audio reminder that prompted patients to use hand sanitizer.

Patient Hand Hygiene Behavior

In this study patient hand hygiene behavior was measured in two different ways. Product Consumption was the measured amount (grams) of hand sanitizer used during the days that the patients were in the hospital (N=75). Product consumption was measured three times for both groups by weighing the product each day after the last time alarm for the electronic audio reminder which was 7pm. Overall, product consumption occurred for both groups, however patients that received the electronic audio reminder (n=41) demonstrated a greater rate of use than patients that did not receive the electronic audio reminder (n=34). The quality of patient hand hygiene behavior were measured using hand swabs to culture for the presence of gram negative organisms and MRSA. Hand cultures was measured on Day 0 and again on Day 3. Gram-negative or MRSA organisms were absent from participants hands on Day 0 and on Day 3.

Product Consumption. Based on product consumption, patient hand hygiene behavior improved for both the EAR and No EAR Groups on all three days. This finding supports previous research about the effectiveness of education to improve behavior of adult patients (Abbas & Armstrong, 2011; Bell & Whiting, 1981; Tuong et al., 2014). Because hand hygiene practice in previous studies indicated that patients clean their hands 40% less often without the assistance of healthcare staff (Barker et al., 2014; Cheng et al., 2016; Srigley et al., 2014), but also that healthcare staff report this added task was difficult to fit into in an already overburdened schedule (Ardizzone et al., 2013; Azim, Juergens, & McLaws, 2016; Cimiotti et al., 2012), this study eliminated healthcare worker participation and tested the use of an audio reminder as

an adjunct to patient education. When the two approaches were used together, the EAR group used approximately 30 grams in comparison of approximately 11 grams of use by the Non-EAR group which was 19 more grams of ABHR by the EAR group over the 3-day study. According to GOJO Industries™ one usual pump of hand-sanitizer releases approximately 1-2 milliliters of solution (J. Arbogast, personal communication, January 23, 2017). This indicates that on average patients in the EAR group cleaned their hands 15 times over the 4-day period or (4-5 times per day). This is more than the 5.5 times over the 4-day period or (1-2 times per day) on average for the group that did not use the EAR. Patient education demonstrated ABHR use for both groups, however the electronic audio reminder, the novel component of this study, substantially increased participants' hand hygiene behavior.

Presence of Bacteria. The quality of patient hand hygiene was measured by hand cultures that were collected on a subset of participants enrolled in the study. Laboratory cultures collected via hand swabs are a classic method for detecting bacteria. Of the 75 participants 21 cultures were collected from participants that received the EAR and 11 participants that did not receive the EAR. Sterile cotton swabs dampened in 0.85% saline were swabbed circularly around the palm, fingers and in between the fingers of the patient's dominant hand, transported and processed within 24 hours in the laboratory. The goal was to measure colony counts, however, no MRSA and gram-negative organisms were identified. One explanation for this finding could be that participants had some level of ABHR use on their days of participation. The other explanation could be the that there were evidence that in the study's hospital setting, pathogens don't typically develop on patient hands until days 4 and 5

(Kundrapu et al., 2014; V. C. K. Sunkesula, Kundrapu, Knighton, Cadnum, & Donskey, 2017b; V. Sunkesula, Kundrapu, et al., 2015c).

Covariates

The five covariates of this study as described below are: upper extremity functionality (QuickDASH & Hand Grip Strength), surgical pain, MRSA of the nares, and level of education.

Upper Extremity Functionality. Upper extremity functionality was operationalized by two tests: *QuickDASH* and the use of a hand dynamometer to gauge *hand grip strength*. In this study neither the QuickDASH or the hand dynamometer was correlated with product consumption or hand cultures, however at the .05 level (2-tailed) there was a negative correlation between QuickDASH ($M = 4.03$ $SD = 10.41$) and hand dynamometer ($M = 48.00$ $SD = 26.43$), $r = -.288$, $p = .012$, $n = 75$. This does make sense according to the literature which provides evidence that older adults experience loss of strength and manual dexterity with aging, (Manini et al., 2013; Martin et al., 2015) which is associated with difficulty performing activities of daily living such as hand hygiene. Using a hand dynamometer as an indicator of Hand Grip Strength is valid and reliable ($ICC > 0.78$, $r > 0.72$) (Mijnarends et al., 2013) that supports the QuickDASH. According to Mathiowetz and colleagues (1985), the normal hand grip strength (mean/ SD) in kilograms for healthy men is 45kg (8.4) for healthy men ages 50-59, 40 kg (8.3) for healthy men ages 60-69, and 33kg (7.8) for health men ages 70 and older. In relation to this study, the average participant in this study was approximately 66 years and the average dynamometer reading was dynamometer range was 48 kg (26.43) which was a greater average than the norms. One consideration could have been the outlier participant

with 140kg hand grip strength. Another explanation for the overall difference between the hand grip strength of the general population of healthy adults and veterans is that veterans often time undergo intense physical training during their time in the military, further studies would be needed to examine the differences.

The lack of relationship between product consumption and hand dexterity and strength can use further study considering hand hygiene is an expected part of daily living, but often a presume practice before activities of daily living such as eating. Theoretically if a person has difficulty with activities of daily living the assumption of being able to perform hand hygiene activities should not be taken lightly as this is an important activity in protecting the immune system in compromised individuals.

Surgical Pain. Pain, mobility and other limitations such as confinement contribute to a patient's inability to participate in hand hygiene (Landers, Abusaleem, Coty, & Bingham, 2012), however pain was not a predictor of hand hygiene practice for this study. Pain scores were based on a scale (0-10) with 0 being no pain to 10 being the worst pain ever felt. Results show that participants in the EAR and No-EAR group had similar pain scores, ($M = 4.89$ $SD = 1.87$) and participant age ($M = 65.93$ $SD = 8.04$), $r = -.288$, $p = .049$, $n = 75$. was negatively correlated indicating that as patients' pain scores went up age went down and vice versa. Emerging evidence supports the relationship between pain tolerance levels, thresholds and age (Pereira et al., 2014). Furthermore, studies demonstrate the negative impact that pain from lower extremity surgery has on activities of daily living such as grooming and hygiene (Amaro et al., 2016; Dorfman et al., 2016; Parkes et al., 2016). Further investigative studies are needed to determine if

these relationships exist in older adult post-surgical populations in relation to hand hygiene behavior.

MRSA in the Nares. At the Louis Stokes Cleveland VA, all patients are screened for MRSA at the time of admission. Previous studies show that patients who are carriers of pathogens have a greater chance of carrying colony forming units (CFUs) on their hands (Istenes et al., 2013; Kundrapu et al., 2014; Sunkesula, Kundrapu, et al., 2015). In this study, however, patients who cultured positive for MRSA in the nares did not have any identifying pathogens from the cultures collected, which was an unexpected finding. Sunkesula and colleagues found that MRSA was present on the hands of 82% of their subjects prior to the one-time use of 2 grams of hand sanitizer. While the colony forming units decreased they were not eliminated (Sunkesula, et al., 2015). Based on this study and studies identifying patients with hand pathogens, I hypothesized that the 10 (13.3%) participants in this study would show some traces of MRSA or gram-negative, however they too had cultures absent of MRSA and or gram-negative bacteria. One explanation for this finding is that regardless of group (EAR or no EAR) participants in this study used approximately 8 grams more of ABHR than participants in the 2015 study done by Sunkesula and colleagues that only examined the use of 2 grams. More use could explain why pathogens were not found even on the hands of patients that carried MRSA in their nares.

Level of Education. Level of education measurement for this study was extracted from the participants' record (CPRS) from within the Nursing Admission assessment. Level of education was not a predictor of product consumption in this study. The

majority of patients reported high school to be their highest level of education attended. Although a relationship did not exist between education and the use of alcohol-based hand rub, there was a relationship between level of education and the first question about *Attitudes and Behaviors*. Attitudes and behaviors ($M = 3.79$ $SD = .473$) and participant level of education ($M = 3$ $SD = .878$), $r = .267$, $p = .021$, $n = 75$. was positively correlated indicating that a relationship existed between the two variables. Patients were asked how much they valued their personal hand hygiene practices at home. Attitude and behaviors of patients was captured by the following questions: (1) At home, how much do you value clean hands, do you think it is (Likert Scale- Not Important=0 to Very Important=4) (2) At home, how often do you clean your hands at home daily? By clean, I mean wash your hands or use hand sanitizer? 0=rarely (0-1 time) to 3=often (>5 times). Of the 75 participants, 80.3% of patients responded as very important to question one and 90.1% responded as almost every time when asked if they cleaned their hands greater than five times per day. Multiple studies have reported that although patients report personal hand hygiene to be important, they don't practice (Burnett, 2009; Istenes et al., 2013; Sunkesula et al., 2015) and/or they do not practice hand hygiene in the hospital as often as they would at home (Barker et al., 2014). The majority of participants in this study did practice hand hygiene where? and expressed its importance.

Level of education in relation to the study of hand hygiene as a correlation and predictor has been studied among nurses and healthcare workers (Duggan, Hensley, Khuder, Papadimos, & Jacobs, 2008; Dunn-Navarra et al., 2011). Duggan and colleagues found that a higher level of education was associated with a lower level of hand hygiene by healthcare workers (2008). Similarly, in relation to patient hand hygiene the highest

qualified nurses were statistically more likely to have a positive attitude towards patient hand hygiene than lower trained nurses ($\chi^2=29.544$, $P<.001$). (Burnett, 2009). The relationships between education, attitudes and behaviors, and influencing factors of patients regarding patient hand hygiene deserve further investigation.

The Study Model

Current hand hygiene models fail to show the significance of patient hand hygiene to infection control. By incorporating patient hand hygiene into a model, such as the Patient Hand Hygiene Model used in this study, healthcare workers and the business industry can visibly see that patient hand hygiene is largely absent despite the perceived benefit of preventing infection transmission. The study model (Figure 1) for this comparative effectiveness study was intended to examine the relationship between patient hand hygiene education and patient hand hygiene behavior with the presence of covariates. The model demonstrated an association between patient hand hygiene education and patient hand hygiene behavior. Patient hand hygiene behavior occurred as a direct result of patient hand hygiene education without the influence of the predictor variables other than the use of the electronic audio reminder. The is evidence provided in the findings of this study to support part of the study model presented in Chapters I, III, and IV. There were statistically significant relationships between the use of the electronic audio reminder product consumption. There was also a relationship between patient attitudes and behaviors towards hand hygiene, education, and active cues (EAR). Pain and age (demographic variable) had a statistical relationship in addition to hand grip strength and the QuickDASH being statistically significant. The model was able to

demonstrate these relationships exist, but also suggested that none of these covariates were a mediator between patient hand hygiene education and behavior. Researchers and health practitioners routinely use behavior change models to promote or improve patients' healthy behaviors. In addition to considering patient beliefs, attitudes and intention (Janz & Becker, 1984) to guide the interventions, the models also frequently incorporate self-efficacy, the individual's confidence in their ability to meet a goal (Bandura, 1982; Hoffman, 2013). Self-Efficacy was not included in this model but I did include one major consideration that is not explicitly explained in existing models such as the Theory for Planned Behavior; that is, the patients' physical ability to perform health behaviors. It is unclear whether this study's findings have to do with the characteristics of the hospitalized patient population studied or if a larger sample size of patients will yield the same outcomes, however further investigation of this patient population with a larger sample size is needed further determine the hypothesized relationships put forth in this study model.

Furthermore, models such as the "Four Moments for Patient's Hand Hygiene" and "Five Moments for Patient's Hand Hygiene" demonstrates that patient innovative approaches can be taken to increase patient hand hygiene, while also reminding healthcare personnel to clean their hands as expected.

Effect Size and Power Analysis. The sample of 75 medical inpatient participants were admitted to the study immediately after non-emergent lower extremity surgical intervention. Randomization software created a sample that was skewed in favor of the EAR group (n=41) in comparison to the No EAR group (n=34), however the

characteristics between both groups were comparable. Using G-Power 3.0 multiple regression with 6 predictors an alpha of .05, power of .80, and effect size of $R^2=.15$ required a total sample size of 56 participants (28 assigned to each group), however complete datasets for 75 participants were obtained. As a result of increasing the sample size, the moderate effect size indicated a greater impact (.11) thus validating the findings beyond the p-level indicating statistical significance for Research Question 1 of the patient hand hygiene model presented in this study.

Study Limitations

Generalizations about this study's findings cannot be made for several reasons including the single setting (one veteran's care medical center) and the sampling (exclusion of non-surgical patients, patients with cognitive disorders, and anyone less than 55 years of age). Considering the resources and participants available, there were limitations to this study. One of the main limitations was the sample size of 75 predominantly male participants. To obtain more representative results, a larger sample that included more female participants is required. A larger sample size would have provided more power to detect differences and a smaller effect size between the group that received the electronic audio reminder and the group that didn't. This study evaluated two forms of an intervention, a cue and education versus education only with both groups using the same alcohol-based hand rub (ABHR). A limitation for obtaining hand hygiene usage from both groups could have been attributed to brand recognition. While the label was covered up with a label "For Patient Use Only" it was still transparent enough for the participants to see the brand through the front or through the back of the clear bottle. Participants

occasionally made comments that they use hand sanitizer at home. One possible explanation could be the physical capability to use the product. While studies examining patient product use of different hand hygiene products at the bedside have been examined (Knighton et al., 2017; Tanner & Mistry, 2011), further studies should evaluate the types of products being used to determine if they are equally proficient in removing pathogens and easy for patients to use. All participants were educated on how to use the hand sanitizer during the time of enrollment, but to better control for brand/product recognition next time it may be helpful to ask participants how often they use it. Of the 41 participants in the EAR group 17 of the participants' family members recorded the "Clean you hand message". This inconsistency could have contributed to differences but on evaluation, the participants that had family members record the message showed no difference in product consumption in comparison with the electronic audio reminder recording from the researcher. It however is important to note, that patients enjoyed hearing their loved ones' voice and family members reported feeling more involved in their care as a result of recording the message. Another limitation to the use of the electronic audio reminder and having the dispenser at the bedside table, was the report from patients that nurses would sometimes move the bedside table away from the bed to connect their intravenous medications and would forget to put the table back. While this finding could have been generalizable to the sample, the results of this study could have been different depending on how many time times this occurred throughout the study. To minimize bias or altering of results, nursing staff was not educated on making sure the bedside table was near the patient.

A major limitation to the study and internal threat to validity that could have impacted my results was *history*. During the study, on June 29th major media outlets took to a story released by the Food and Drug Administration (FDA) regarding the safety and effectiveness of hand sanitizer products (Pawlowski, 2016). Although FDA in early September 2016 did come back to state that it was only regarding products containing Triclosan (an ingredient not found in ABHR hand sanitizer) (Commissioner, 2016), patients asked if the product was safe for them to use based on what they saw in the media. While, there was a considerable amount of hand sanitizer used over three days, the amount of hand sanitizer used could have been altered by this.

In addressing the amount of hand sanitizer used, while one full pump of hand sanitizer of ABHR from an 8. oz bottle of hand sanitizer is 2 milliliters, this study was limited in gauging how many times and on average how much hand sanitizer was used per participant. To avoid this potential limitation next time, I would consider advising the participants to fully push the nozzle down for a full amount of hand sanitizer per use. A control group of participants was not included in this study, however previous studies conducted at this medical center with a sample of participants with similar demographics were found to have poor hand hygiene practices prior to educational interventions (Sunkesula, et al., 2015; Sunkesula et al., 2017)

The attrition rate for this study was lower than expected for the sample size and while the sample size for this study was only 75, it provides useful preliminary data for follow-up studies. For future studies in this area, consideration when

measuring patient hand hygiene behavior by hand cultures should consider patient populations residing in hospital settings long than five days especially for surgical patients with the expectation of pain after surgery. Medications such as opioids for pain and diphenhydramine to offset the itching and promote sleep could have had an effect of participants' ability to practice, however despite these possible limitations participants of both groups demonstrated some level of practice. Additional statistical analysis of data could potentially yield more definitive similarities and differences not identified in these analyses. Consequently, the findings lay the ground work for future patient-centered hand hygiene research.

Implications for Practice and Policy

Patient Hand Hygiene Education

The importance of patient hand hygiene should be discussed in all patient care settings and among nurse educators so that information is shared with students and during staff development. This study demonstrated that multi-modal education can improve self-management of hand hygiene practices of older adults. Although the target of this study was to examine the difference in ABHR consumption for two groups that received education and a cue versus no cu, this study contributes to the science demonstrating that older adults can and will perform hand hygiene with minimal assistance if provided with relatively little education and resources. Furthermore, the assumption that only healthcare workers should perform hand hygiene to prevent infections deserves further investigation based on the findings of the literature review indicating that patients carry pathogens on their hands and have poor hand hygiene practice in healthcare-settings (Sunkesula et al., 2017a).

Electronic-Assisted Reminders for Self-Management

The lack of research and documentation on the topic of patient hand hygiene intervention studies prompted this comparative effectiveness study to determine if the use of multimodal education (handout, video and EAR) had an effect on patient hand hygiene practice. Furthermore, it used an electronic audio reminder to prompt patients to clean their hands. While the patient handout and video was provided to patients as a passive cue to clean their hands, the electronic audio reminder was an active cue that demonstrated its impact on patient hand hygiene. Thus, in this study, I identified one specific variable that had a significant influence on product consumption. With nurse shortages, medical errors, and the challenges of patient: staff ratios, the use of electronic-assisted reminders can be used to help the patient stay on course with their care and become an equal partner in achieving their optimal level of health. The important point to take from this study is that the methods used to increase patient hand hygiene prevents a practice that patients can perform independently that would otherwise increase healthcare worker workload. To date, even though hospitals routinely provide hand hygiene products, much of the disparity between belief and behavior has been largely attributed to the inability of patients to clean their hands without the assistance of healthcare workers. Consequently, healthcare workers facilitating the hand hygiene practices of patients at important times such as urinal use or meal times does yield higher rates of patient hand hygiene practice (Sunkesula et al., 2015), however patient-staff ratios make this impractical. The electronic audio reminder was used to serve as a reminder from healthcare workers or loved ones thus helping the patient to accomplish the goal of clean hands without the assistance of healthcare staff. Furthermore, the use of devices to assist

with the provision of care can also minimize nurse burden. This is the first known study that utilizes a voice-audio recorded reminder to assist patients with their independent behavior of hand hygiene. The findings from this study could lead to other innovative pathways for simple technology to assist with imbalanced patient: staff ratios while also increasing independent patient hand hygiene practice.

Improved Patient Hand Hygiene

Patient hand hygiene is an emerging topic in healthcare. Healthcare organizations are beginning to understand the impact that poor patient hand hygiene potentially has on their costs, quality and safety metrics, and overall patient experience. Currently, governing entities and accrediting bodies with established mandates do not incorporate patient hand hygiene as a strategy for infection prevention. As studies continue to reveal reasons of poor motivation, limited mobility, and inadequate hand hygiene facilities interventions are needed to offset these barriers. Studies similar to this one can guide the widespread formation and implementation of guidelines for patient hand hygiene as part of infection prevention policies. Without excluding the current infection prevention methods, this study provides the beginning steps of a comprehensive, relatively inexpensive method for a patient-centered approach to infection prevention.

Recommendations for Future Research

While this study is not generalizable, it suggests tools and methods that can be appropriately used for patients with varying ages, backgrounds, and health problem including our aging population that will have some level of functional limitation. The next steps in research are to refine and validate the educational intervention in more diverse populations including women and children and in different healthcare settings.

Furthermore, the evaluation of hand hygiene products provided to patients and the cost considerations for healthcare organizations should be studied. Patient hand hygiene could also be studied by the infection prevention business industry to assess the patient-centeredness of products and services that will improve patient hand hygiene practice.

Researchers are encouraged to replicate this study or design other studies using the patient hand hygiene model (Figure 1). Inquiries deserving further investigation in the area of patient hand hygiene include understanding electronic audio reminder prompts among the “Four Moments for Patients’ Hand Hygiene”, the comparison of hand hygiene practices between ambulatory and non-ambulatory patients, and the co-education of hand hygiene practices among both patients and healthcare workers.

Conclusion

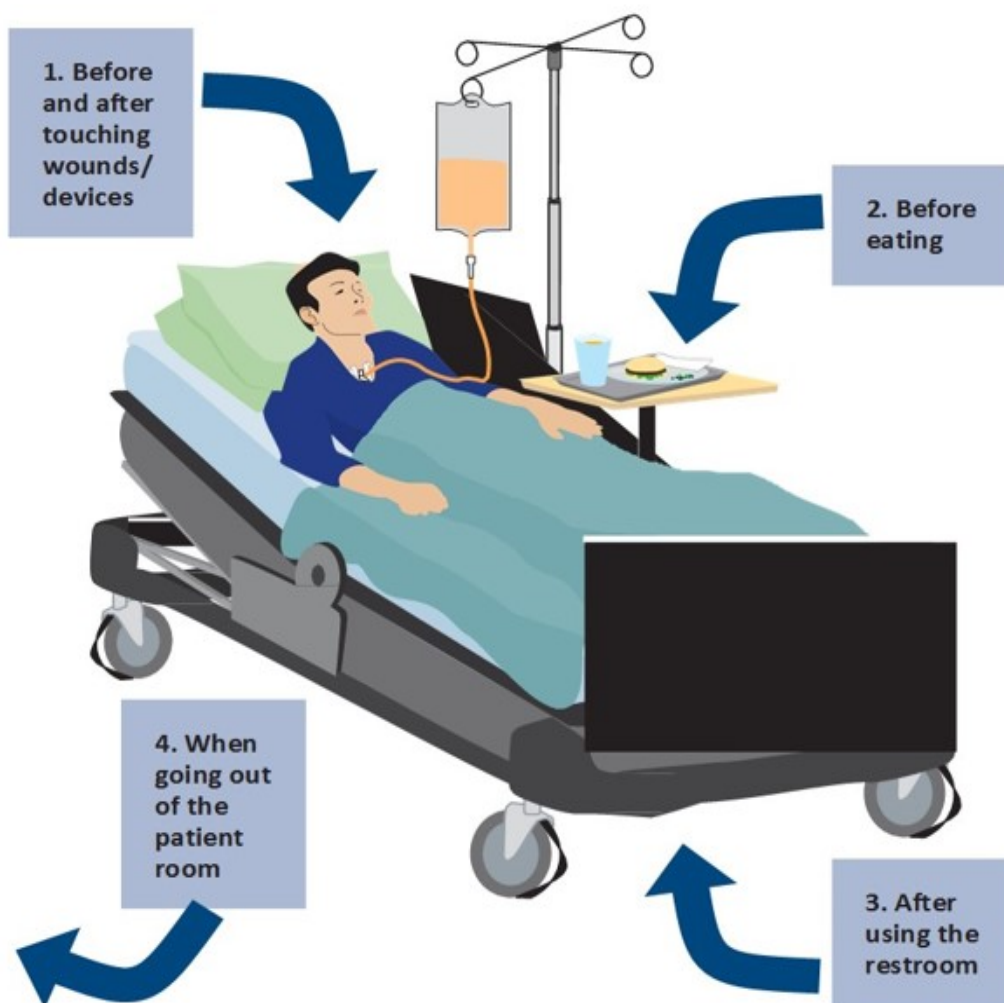
Over a century ago, Florence Nightingale made note of the importance of hygiene including the hands of the soldiers she cared for. She also recorded the deaths that occurred due to infection and hypothesized a relationship between cleanliness and control of pathogen transmission. In the 21st century, we know that pathogens are present in human body substances and there are practices to minimize them. However, studies show that patients have decreased patient hand hygiene practices when in healthcare settings (Ardizzzone et al., 2013; Srigley et al., 2014). Therefore, we need to continue to build evidence about patient hand hygiene and its contributions to healthcare-associated infections. Furthermore,

Patient-centered care is considered to be the foundation of quality. To improve patients’ hand hygiene practices, it is important to address barriers preventing them from being able to practice hand hygiene at times that they deem important to them. Barriers

identified that prevent patients from cleaning their hands in addition to physical and functional limitations, mobility, and staff being too busy to assist them is the underlying theme of resources encouraging self-management practices. Patients neglect to practice hand hygiene independently argues for the need to further investigation other influencing barriers to independent patient hand hygiene practice. Just as we have the freedom to clean our hands in our home settings, in public and as well see fit, patients have the same right when receiving care in an institution and they should be considered an equal partner in eliminating healthcare-associated infections.

Appendix A. Four Moments Handout

Patient's Four Moments for Hand Hygiene



Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u>	VAMC: <u>Cleveland (541)</u>
Consent Version Date: <u>7/4/16</u>	

DESCRIPTION OF RESEARCH BY INVESTIGATOR

NOTE: The consent form must include the following section headings:

- | | |
|------------------------------------|--|
| I. Purpose of the Study | VI. Alternative Procedure(s)/Treatment(s) |
| II. Description of the Study | VII. Privacy, Confidentiality, and Use of Research Results |
| III. Inconveniences | VIII. Special Circumstances |
| IV. Discomforts/Risks/Side Effects | IX. Contact Information |
| V. Benefits | |

TO POTENTIAL PARTICIPANTS: Federal regulations require written informed consent before participation in a research study. This is to be certain that research volunteers know the nature and risks of the study, so they can make an informed decision about participation. You are asked to read the following information and discuss it with the investigator, so that you understand this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate. It is also important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part in the research is entirely voluntary.
2. You may not personally benefit from taking part in the research but the knowledge obtained may help the health care professionals caring for you to better understand the disease/condition and how to treat it.
3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.
4. If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies, which may affect your willingness to continue in the research project, your doctor will discuss the new information with you and will help you make a decision about continuing in the research.

VA FORM 10-1086

Template revised – October 2015

Cleveland VAMC IRB approved
the use of this version on 7/27/16

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 2 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

5. The purpose of the research, how it will be done, and what your part in the research will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information, which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions, concerns, or complaints you have about this research with the research staff members.

I. PURPOSE OF THE STUDY:

You are being asked to participate in this research study because you are an adult admitted to the Cleveland VA hospital for an orthopedic or podiatry surgery to your hip, leg, foot, and/or toe(s) but the study is not about surgery. The study is about hand hygiene and infection prevention.

The purpose of this study is to help researchers, clinicians, families, and veterans better understand hand hygiene practice of veterans who are hospitalized for orthopedic and podiatry surgery. All study procedures will be conducted at the Louis Stokes Cleveland Department of Veteran Affairs Medical Center (LSCDVAMC).

Approximately 125 veterans will be asked to participate in the study from the LSCDVAMC.

II. DESCRIPTION OF STUDY:

There are two groups of subjects in this study. Group assignment is determined randomly (by chance). This means that we will use a computer software program that will randomly choose if you will belong to Group 1 or Group 2. This process is similar to flipping a coin.

- If you are in Group 1, you will complete the study protocol outlined below AND you will receive a battery-operated electronic reminder, which looks like a small alarm clock, that will sit on your bedside table. This clock will tell you "Please Clean Your Hands" at the following times: 12pm (before lunch), 5pm (before dinner), and 7pm (before bedtime).
- If you are in Group 2, you will complete the study protocol outlined below.

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 3 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

1. You will be asked to squeeze a hand dynamometer three times. A hand dynamometer is a sturdy metal spring. You will anchor one end by squeezing it and the other end will measure the force this is read from the scale on the front. This will help us to understand how strong your hands are. It will be similar to squeezing a bar.
2. You will be asked two questions about hand hygiene importance and be asked 11 questions about your arm shoulders and hand use and strength.
3. You will be provided with an educational handout and watch an educational video about hand hygiene
4. You should clean your hands at the times indicated on the handout.
5. You will be provided with a bottle of hand sanitizer and instructed how to use it. **This bottle of hand sanitizer (alcohol-based hand rub) is marked for your use only.** Your family can use other resources in the room to clean their hands.
6. If you get a reminder from the electronic audio reminder (a talking alarm clock) please clean your hands at that time.
7. Following enrollment in the study, the same randomization software will be used to select for a small group of participants to have 2 hand swabs collected, once 24 hours after admission and again on the third day after admission. A hand swab involves rubbing a cotton swab over your finger tips and in between your fingers of the hand you use the most. Hand swabs take 1-2 minutes. If you decline to have hand swabs you can still be in the study. Please indicate with your initials your willingness to have hand swabs.
8. Once a day during the length of your stay, we will come to your room to check your device and to measure your hand sanitizer bottle. If you are chosen to have your hands swabbed, the swab will be taken during this time. The total time of visit should last no longer than 10 minutes. Please feel free to ask any questions during this time.

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 4 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

How Long Will You Be in The Study?

The initial study visit will last no longer than 30 minutes including time to set up.

Each follow-up visit will last no longer than 10 minutes. You will have approximately 3-5 follow-up visits.

When you are released from the hospital your study participation will be complete.

Randomization/Study Intervention

You will be randomly assigned to one of two groups: the experimental group (the group that will receive patient hand hygiene education by handout and video with the addition of a talking electronic audio reminder for hand hygiene practice) or control group (you will receive patient hand hygiene education by handout and video only and a non-talking reminder system in your room). You will have a 50% chance of being assigned to either group. Randomization software will be used to assign you to either group which we will indicate by using a sticker.

Discontinuation Visit

- If you decide to withdraw from the study before the study is over, we will ask for your reason and record the information to help us improve future studies. This information is voluntary and you can decline to provide.
- We will remove the study materials from your room, however you will be allowed to keep the hand sanitizer.
- The information collected about you before you withdraw may be used in the study findings.

End of Study

The research team will not have individual results readily available to you after each day and not until months after the end of the study period. However if you would like to receive information about the study results in general please feel free to contact Shanina Knighton using the contact information provided on this consent.

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 5 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

III. INCONVENIENCES:

- The time involved with enrolling you in the study
- The time it will take the PI to collect data which will require us being in your room
- Cleaning your hands at certain time intervals
- If you are a part of the group selected to receive the electronic audio reminder, the electronic audio reminder can be an inconvenience while you are resting or it may be alarming at unexpected times
- If you are selected to have your hands swabbed, the couple of minutes used to complete this process can be an inconvenience

IV. DISCOMFORTS / RISKS / SIDE EFFECTS:

Although rare with such short use, alcohol-based hand rub can result in skin irritation and peeling. If this occurs, you will be removed from the study and the staff will be notified of your condition and you will receive appropriate treatment to the affected area. Standard Precautions will be maintained for equipment: the digital scale used to measure your hand hygiene product use and the electronic audio reminder. These two items will be cleaned between patients to avoid transferring germs between participants. The practice of hand hygiene is one of the most important ways to prevent infection; however, this study does not guarantee that your infection risks will be minimized. There also is the potential risk for the loss of confidentiality of your data. Every effort will be made to keep your information confidential; however, it cannot be 100% guaranteed.

V. BENEFITS:

The results of this study will inform researchers and clinicians on better ways to help future patients perform hand hygiene in the hospital.

VI. ALTERNATIVE PROCEDURE(S) / TREATMENT(S):

The only alternative is to not participate in this study.

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 6 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

VII. PRIVACY, CONFIDENTIALITY, AND USE OF RESEARCH RESULTS:

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974.

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. The research records will be kept in a password-protected computer file that only the study team has access to. Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any presentations or publications from this information will not identify you.

VA policy requires us to keep study records indefinitely. However, protections will be put in place to be sure that this information is kept confidential.

In order to comply with federal regulations, research records identifying you may be reviewed by the following:

- Authorized representatives of the LSCDVAMC Institutional Review board and VA
- Federal Agencies such as the Government Accounting Office (GAO), the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP)
- Case Western Reserve University (CWRU)

By joining this study, you give the investigators your permission for them to collect data from your medical records to determine if you are eligible and if you remain eligible to participate in the study.

When your information is given to other researchers working with this study, your information will be labeled with a unique code. Only Shanina Knighton, the PI, will be able to identify you. The paper research records will be kept in a locked filing cabinet in a locked office. The electronic research records will be kept on a password-protected computer in the PI's office. This information will be secured on a network drive, accessible to only the PI.

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 7 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

New Findings:

You will be told by the PI, Shanina Knighton of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

Financial Considerations

Your participation in this research study will be done at no cost to you. You will receive \$10 in cash for your participation in the study after the completion of your last weighing of your hand sanitizer. You will be asked to sign for the \$10 upon receipt of it to indicate that you received it. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Ending Participation

The investigators may stop your participation in this study without your consent, for example, if they think that it will be in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason. You are not obligated stay enrolled in the study and can withdrawal at any time.

Compensation for Research-Related Injury

If you sustain injury as a direct result of your study participation, medical care will be provided by the LSCDVAMC at no cost to you. Financial compensation for such things as lost wages, disability, or discomfort due to an injury may not be available.

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 8 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

IX. CONTACT INFORMATION

To answer questions about the research or if you sustain a research related injury contact the following:

- During the Day: Shanina Knighton [REDACTED]
- After Hours: Shanina Knighton [REDACTED]

For answers to questions about rights as a research participant or to voice a concern or complaint contact the following:

- The Research Administrative Officer at (216) [REDACTED]
- The LSCDVAMC Patient Representative at (216) [REDACTED]

If you wish to speak with someone other than study staff to provide input concerning the research process, check whether a study is being conducted at the LSCDVAMC, and if study staff are permitted to represent the study contact :

- The LSCDVAMC Institutional Review Board Office at (216) [REDACTED]

Appendix B. Informed Consent

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 9 of 9)
Subject Name: _____ Date: _____	
Title of Study: <u>Patient-Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults</u>	
Principal Investigator: <u>Shanina Knighton BA, BSN, RN</u> VAMC: <u>Cleveland (541)</u>	
Consent Version Date: <u>7/4/16</u>	

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the preceding information.

Dr./Mr./Ms. _____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state and federal agencies.

I understand my rights as a subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed consent form or a photocopy of it. I understand that in signing this consent form I do not waive my legal rights nor release the LSCDVAMC from liability for negligence.

Subject's Signature _____ Date __ / __ / __

Signature of Subject's Representative _____ Date __ / __ / __
 (if subject not competent)

Printed name _____

Signature of Person Obtaining Consent _____ Date __ / __ / __

Appendix C. Participant Form

Appendices and References for Shanina Knighton Patient Hand Hygiene Study 2016

1

PARTICIPANT ID _____

Date and time of study enrollment and ending:

Began at _____ am/pm on ____/____/16

Ended at _____ am/pm on ____/____/16

Participant did not complete study (Circle statement if Applicable) * see reason below

Electronic Reminder

____ Yes=1 ____ No=0

Unit: _____ Patient Room #: _____

Age: _____ Ethnicity: _____ Gender: M F *please circle*MRSA Nares: _____ Positive (1) _____ Negative (0) *please check*

1. At Home how much do you value clean hands? Do you think it is which of the following:

_____ (Not Important =0) _____ (Low Importance =1)

_____ (Slightly Important= 2) _____ (Neutral =3)

_____ (Moderately Important =4) _____ (Very Important =5)

2. At home how often do you clean your hands at home daily? By clean, I mean wash your hands or use hand sanitizer?

Rarely=1 _____ (0-1 times) =2 _____ often (>5 times) =3 _____

Hand Strength: Dynamometer (kg) (Collected Day 1) _____

Surgical Pain (0-10) Collected from CPRS (Last Reading):

Day 1 ____ D ____ E ____ N Day 2 ____ D ____ E ____ N

Day 3 ____ D ____ E ____ N Day 4 ____ D ____ E ____ N

Approved

Cleveland VAMC
Institutional Review Board

Appendix C. Participant Form

Appendices and References for Shanina Knighton Patient Hand Hygiene Study 2016

2

PARTICIPANT ID _____

QuickDASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. (circle number)

	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? (circle number)	1	2	3	4	5

QuickDASH DISABILITY/SYMPTOM SCORE = $\left(\frac{\text{sum of } n \text{ responses}}{n} - 1 \right) \times 25$, where n is equal to the number of completed responses.

A QuickDASH score may not be calculated if there is greater than 1 missing item.

Dash Score _____

Approved
7/27/16
Cleveland VAMC
Institutional Review Board

Appendix C. Participant Form

Appendices and References for Shanina Knighton Patient Hand Hygiene Study 2016

3

PARTICIPANT ID _____

Type of Lower Extremity Surgery: ____ Hip ____ Knee ____ Foot ____ Toe

Highest Level of Education Attended: ____ Grade school ____ Middle school
____ High school ____ College

Quality check every 24hrs complete

Day 1 _____ Day 2 _____ Day 3 _____ Day 4 _____

Time Recorded _____ pm _____ pm _____ pm _____ pm

Product Consumption Measured by Electronic Digital Scale

Day 1 _____ oz. Day 2 _____ oz. Day 3 _____ oz. Day 4 _____ oz.

Time Recorded _____ pm _____ pm _____ pm _____ pm

*Comments

Approved
7/27/16
 Cleveland VAMC
 Institutional Review Board

Appendix C. Participant Form

Appendices and References for Shanina Knighton Patient Hand Hygiene Study 2016

4

PARTICIPANT ID _____**Bacterial Hand Cultures Day 1 Recording (Enrollment)**

Date: _____ Time: _____

MRSA Colony Forming Units (Recording & Notes) _____ CFUs

Gram-Negative Colony Forming Units (Recording & Notes) _____ CFUs

Bacterial Hand Cultures Day 4 or 5 Recording (End of Study)

Date: _____ Time: _____

MRSA Colony Forming Units (Recording & Notes) _____ CFUs

Gram-Negative Colony Forming Units (Recording & Notes) _____ CFUs

Approved
 7/27/16

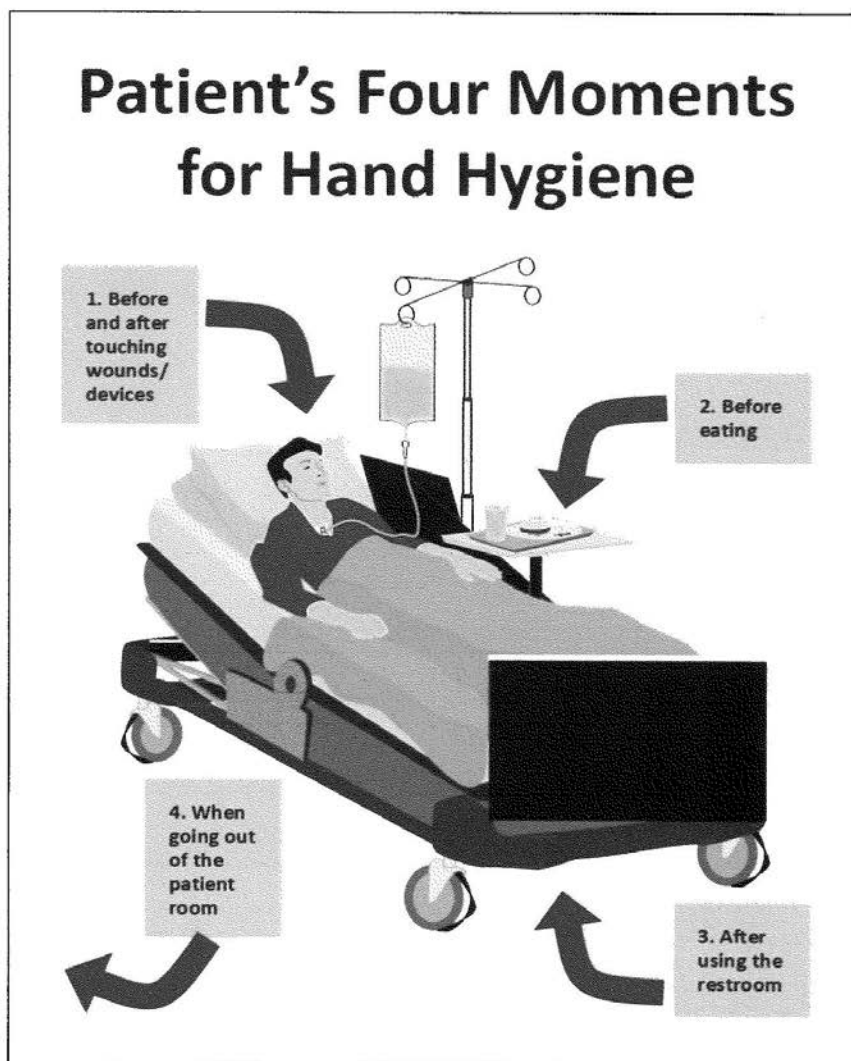
 Cleveland VAMC
 Institutional Review Board

Appendix C. Participant Form

Appendices and References for Shanina Knighton Patient Hand Hygiene Study 2016

5

PARTICIPANT ID _____



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Cleveland VAMC
Institutional Review Board

Appendix D. Coefficients

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	5.297	8.061		.657	.513	-10.789	21.382					
	Dynan Dynamometer	.134	.070	.208	1.916	.060	-.006	.273	.393	.226	.181	.758	1.318
	Average of 3 scores												
	EAR Patient Get	16.327	3.448	.482	4.735	.000	9.447	23.207	.563	.498	.448	.866	1.155
	Electronic Audio Reminders?												
	Edu High Level of Education Attended	-1.183	1.900	-.061	-.623	.536	-4.974	2.608	.043	-.075	-.059	.930	1.075
	MRSA MRSA Status from Admission	-.644	4.799	-.013	-.134	.894	-10.220	8.931	-.088	-.016	-.013	.958	1.043
	Painavg	1.050	.865	.116	1.213	.229	-.677	2.776	.081	.146	.115	.986	1.014
	QUICKdashTot Total	-.202	.162	-.124	-1.248	.216	-.526	.121	-.238	-.150	-.118	.906	1.104
	QuickDASH Score												

a. Dependent Variable: Diffcons Difference in product consumption between day 0 and 3

Appendix E. IRB Approval Letter

**DEPARTMENT OF
VETERANS AFFAIRS****Memorandum**

August 8, 2016

Shanina Knighton, BA, BSN

RE: IRB #16023-H16**At: Louis Stokes Cleveland DVA Medical Center**

Dear Ms. Knighton:

Protocol Title: Patient Centered Infection Prevention: A Hand Hygiene Intervention for Hospitalized Adults

The protocol modifications and modified consent form for the above referenced study were reviewed and APPROVED by the Institutional Review Board of the Cleveland VA Medical Center on July 27, 2016, under expedited review as minor changes in previously approved research 45 CFR 46 110(b)(2).

Please assure that each subject is given only this version of the consent forms to sign. All other versions of the consent forms should be filed in history to protect against accidental use.

Internal #: 6973**Expiration Date:** 5/24/2017

Description: Modification - PI has received funding, has added compensation for the subjects and has revised a data collection form. Revised Research Plan, Consent Form and Data Collection Form submitted.

IRB ACTION: APPROVED**Risk Determination:** Remains Minimal Risk**Approval Period:** Unchanged

The Expiration Date for this whole study is 5/24/2017. Please note that the Expiration Date has not changed since the study was last approved as a New Study or as a Continuing Review submission. Protocol modifications do not advance the approval period of the whole study. Although the Board will normally give notice of the expiration of approval, it is the investigator's responsibility to note the study's expiration date and submit the continuing review documents on a timely basis maintain approval.

If you have any questions, please contact the IRB office at (216) [REDACTED]

The Human Research Protection Program at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center operates under the HHS Federal Wide Assurance number FWA00004231.

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